Environmental Assessment of

Joint Vaccine Acquisition Program-Sponsored Activities at the Battelle Memorial Institute West Jefferson Complex, West Jefferson, Ohio

Prepared by: Joint Vaccine Acquisition Program

Project Management Office

1436 Porter Street

Fort Detrick, MD 21702-5041



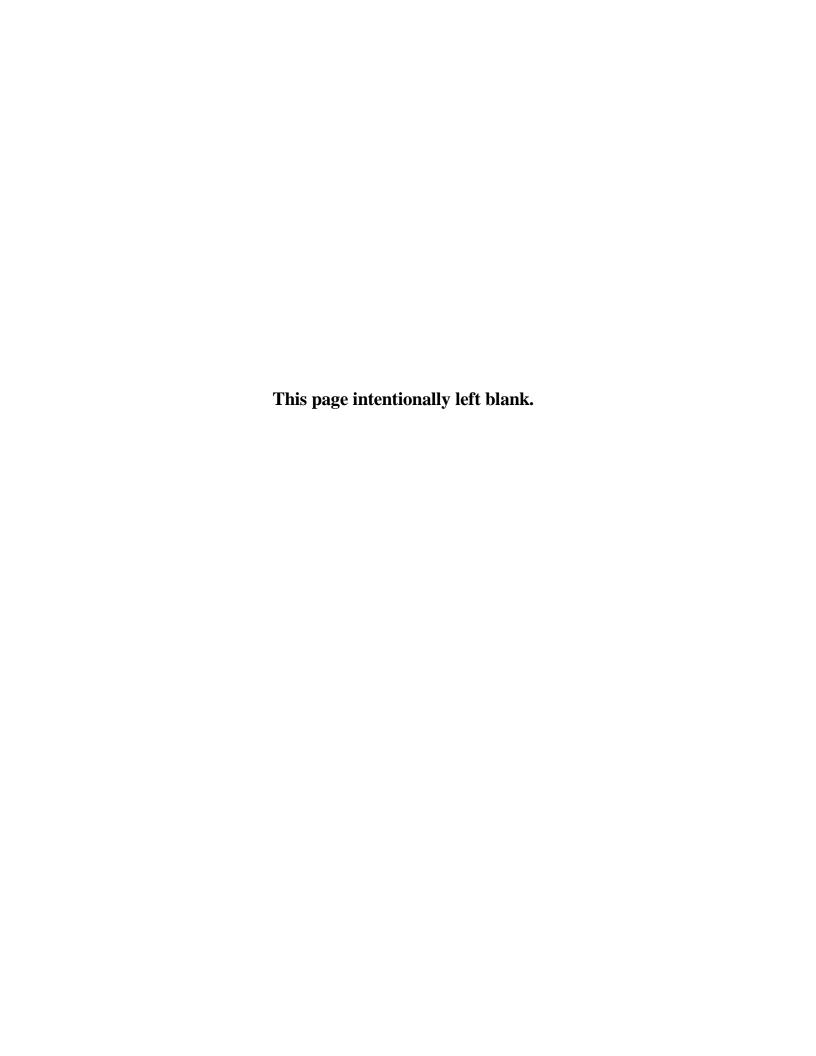
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EXECUTIVE SUMMARY

This Environmental Assessment (EA) was prepared in accordance with guidance provided in the *Joint Vaccine Acquisition Program Project Management Office Environmental Policy and Procedures*, dated November 1998, and Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988, implementing the National Environmental Policy Act (NEPA) (42 U.S. Code [USC] 4321-4347). This EA, *Environmental Assessment of Joint Vaccine Acquisition Program-Sponsored Activities at the Battelle Memorial Institute West Jefferson Complex, West Jefferson, Ohio*, was prepared by the Joint Vaccine Acquisition Program (JVAP) Project Management Office (PMO) with assistance from Science Applications International Corporation (SAIC) and its subcontractor, BSA Environmental Services, Inc., under Contract Number DAMD17-98-D-022.

The Department of Defense (DoD) is implementing the JVAP through the Joint Program Office for Biological Defense (JPO BD), with the Department of the Army (DA) serving as the DoD executive agency. The JVAP Project Manager (PM) reports to the Joint Program Manager for Biological Defense (JPM-BD) and is responsible for directing, managing, and administering the JVAP and thus serves as the lead in ensuring NEPA compliance for JVAP actions. Pursuant to agreement, the JVAP PM obtains environmental support from the U.S. Army Medical Research and Materiel Command (USAMRMC).

This EA describes and analyzes the potential adverse environmental impacts, including human health impacts, associated with conducting the proposed JVAP-sponsored activities at the Battelle Memorial Institute West Jefferson Complex, located in West Jefferson, Ohio. Any contemplated or likely action is considered a proposed activity whether or not it actually materializes. This analysis considers impacts expected from conducting the proposed activities, cumulative impacts that might occur after several years, impacts resulting from association with other activities in the area, and impacts resulting from an accident or incident. The proposed activities are required components of JVAP efforts to develop biological defense products (e.g., vaccines) licensed by the U.S. Food and Drug Administration (FDA).

During the preparation of this EA, two alternatives to the proposed action were considered: conduct the proposed JVAP-sponsored activities at another facility (Alternative II); and to not conduct proposed JVAP-sponsored activities (Alternative III, no action). This EA characterizes the reasonably predictable environmental impacts, including impacts to human health, that might result from conducting either the proposed activities at the Battelle West Jefferson site (Alternative I, the preferred alternative) or the alternatives considered.

The principal conclusions of this EA are: (1) the conduct of the proposed JVAP-sponsored activities (Alternative I, the preferred alternative) is not expected to result in significant adverse environmental impacts; (2) implementing the preferred alternative will likely result in important benefits to the U.S. by enhancing progress toward developing acceptable vaccines against validated biological warfare threats; (3) conducting the proposed activities at another facility (Alternative II) will not likely alter the potential for environmental impact and is unlikely to offer significant advantage over the preferred alternative; and (4) not conducting the proposed JVAP-sponsored activities (Alternative III, no action) will eliminate the negligible environmental impacts associated with conducting development, testing, and evaluation activities but will also impede the development and licensure of biological defense products effective against biological warfare agents.

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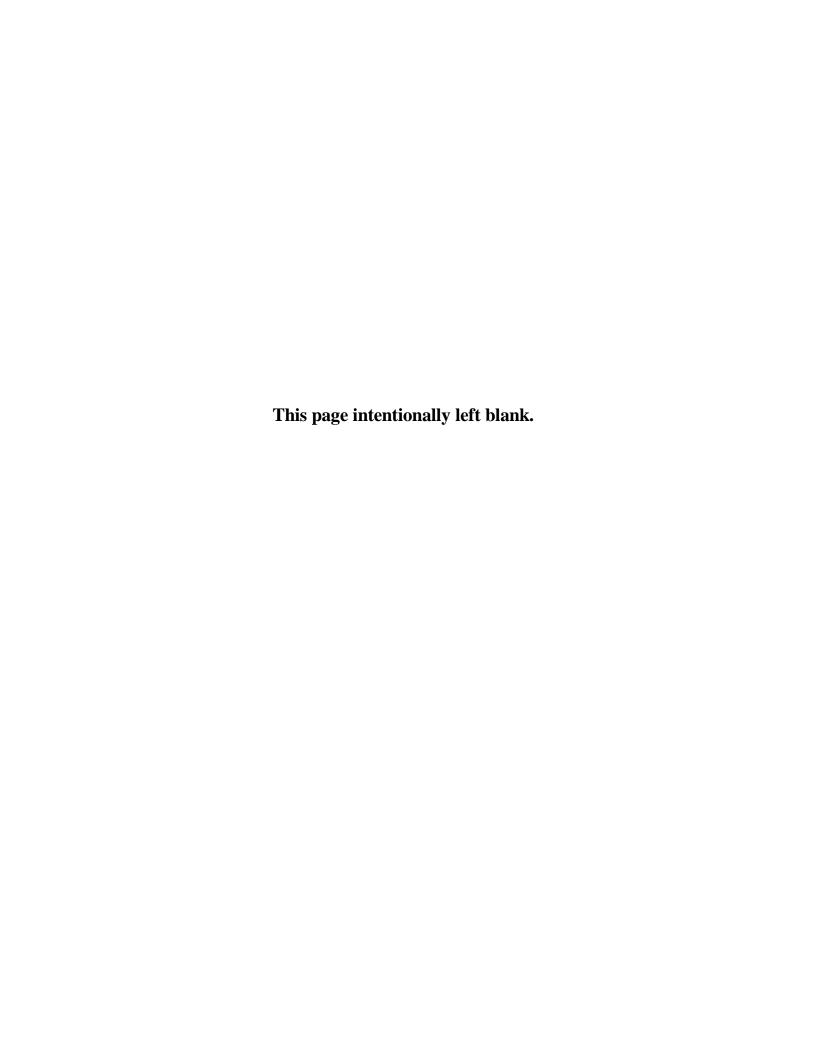


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1.0 PURPOSE AND NEED FOR THE PROPOSED ACTION

Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect U.S. military personnel from biological warfare agents. The Joint Vaccine Acquisition Program (JVAP) is funded by Congress to implement U.S. policy for biological defense and to develop, produce, and stockpile biological products (e.g., vaccines) licensed by the FDA that are otherwise unavailable and for which a need has been determined [Department of Defense (DoD) Directive 6205.3, *Immunization Program for Biological Warfare Defense*].

The DoD implements the JVAP through the Joint Program Office for Biological Defense (JPO BD) with the Army serving as DoD executive agency. The charter for the JPO BD was approved by the Deputy Secretary of Defense on May 19, 1994 and the Joint Program Manager for Biological Defense (JPM-BD) was assigned responsibility for the development, licensure, procurement, and stockpiling of biological defense vaccines. The JVAP Project Manager (PM) reports to the JPM-BD and is responsible for directing, managing, and administering the JVAP and thus serves as the lead in ensuring NEPA compliance for JVAP actions. In 1997, the JPO BD selected and U.S. Army Medical Research Acquisition Activity (USAMRAA) awarded a prime systems contract (PSC) to DynPort, Limited Liability Corporation (LLC) through a competitive bid process to manage the development, licensure, production and storage of JVAP biological defense vaccines. Under this PSC, DynPort LLC provides management services, personnel, facilities, equipment, materials, supplies, and documentation necessary to develop and produce the FDA-licensed vaccines specified by the DoD. DynPort LLC manages the development of vaccine candidates at various stages of development and coordinates the testing and evaluation that are required for FDA licensure. The vaccines under development for the JPO BD through the JVAP are at various stages with respect to FDA licensure, and development, testing, and evaluation activities are, or may be, conducted by several Department of the Army (DA) and private sector entities, including the Battelle Memorial Institute West Jefferson Complex.

A principal objective of the JVAP is to complete the development and testing required for FDA licensing of biological defense vaccines. The proposed action (Alternative I, preferred alternative) and subject of this Environmental Assessment (EA) is the conduct of JVAP-sponsored activities associated with the development and testing of biological defense vaccine candidates at the Battelle Memorial Institute West Jefferson Complex (hereinafter, the Battelle West Jefferson site). The proposed activities examined in this EA include laboratory activities that are required to evaluate the safety and efficacy of vaccines under development by the JVAP and are required components of the FDA licensing process. These testing activities will involve the use of etiologic agents (viable viral or microbial agents and toxins which cause, or may cause, human disease) and will require the use of laboratories, procedures, and associated expertise for achieving biological containment at biosafety levels 2 and 3 (BSL-2 and BSL-3). A detailed description of proposed JVAP-sponsored activities at the Battelle West Jefferson site is found in Section 2.0 of this EA. The proposed activities are viewed as necessary components of JVAP efforts to develop FDA-licensed biological products (e.g., vaccines) for use against biological warfare threats. This EA describes and analyzes the potential adverse environmental impacts, including human health impacts, associated with the proposed activities.

The National Environmental Policy Act (NEPA) (42 U.S. Code [USC] 4321-4347) requires that each Federal agency consider the potential environmental impacts associated with proposed major

actions. The Council on Environmental Quality (CEQ), Executive Office of the President, has promulgated regulations implementing NEPA (40 Code of Federal Regulations [CFR] Parts 1500-1508). Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988 (32 CFR 651), is the DA's implementation of NEPA and the CEQ regulations. The JVAP PM is responsible for directing, managing, and administering the JVAP and thus serves as the lead in ensuring NEPA compliance for JVAP actions. JVAP environmental policy requires that an EA be prepared in accordance with AR 200-2 and CEQ regulations for proposed actions requiring the use of BSL-3 or BSL-4 facilities and procedures. This EA was prepared in accordance with AR 200-2 and CEQ regulations.

Programmatic aspects of the JVAP were previously evaluated within a NEPA context. The *Joint Vaccine Acquisition Program Final Programmatic Environmental Assessment* (JVAP PEA) was prepared by the JVAP Project Management Office (PMO) in 1997 to examine the possible and probable environmental impacts of JVAP activities. Following public review of the analysis, a Finding of No Significant Impact was published in the Federal Register. The JVAP PEA, while deferring detailed analyses of the conduct of the program at specific locations, concluded that the potential for adverse impacts to the environment, including human health impacts, associated with the development, production, and fielding of JVAP-sponsored vaccines was minimal. This EA considers the impacts anticipated from conducting the proposed JVAP-sponsored activities, the cumulative impacts that might occur after several years, the impacts resulting from association with other activities in the area, and the impacts that might result from an accident or incident. Two alternatives to the proposed action are also evaluated (see Sections 3 and 5).

2.0 DESCRIPTION OF THE PROPOSED ACTION

2.1 Introduction

The purpose of this section is to describe the proposed action so that the potential environmental impacts from its implementation may be analyzed (see Section 5.0). In this section the proposed activities, facilities, and operations are described as are the operational and engineering features designed to mitigate (lessen or alleviate) potential environmental impacts of the proposed JVAP-sponsored activities.

2.2 ORGANIZATION, LOCATION, AND FACILITIES

The JVAP-sponsored activities under consideration are proposed for potential execution at the site of the Battelle West Jefferson Complex, through a subcontracting agreement with DynCorp, LLC, the JVAP PSC. This complex is located in West Jefferson, Ohio, on a 1,187-acre site (see Figure 2-1) owned and managed by Battelle Columbus Operations and used for the research, development, testing, and evaluation projects that Battelle performs under contract for various clients. The Battelle West Jefferson facilities being considered for the JVAP-sponsored work include two non-adjacent buildings, JM-1 (West Jefferson site, middle area, Building 1) and JS-1 (West Jefferson site, south area, Building 1). Both of these buildings are designed and equipped with the type of specialized equipment necessary to contain the etiologic agents that are proposed for use in the animal and laboratory testing of biological defense vaccines.

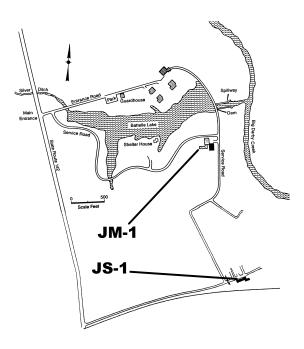


Figure 2-1. Battelle West Jefferson Complex

An etiologic agent is defined as any viable viral or microbial agent or its molecular component and any natural toxin that causes, or may cause, human disease. Special biosafety level procedures, equipment and facility design and construction are employed to protect laboratory workers and the environment from exposure to etiologic agents. These are detailed in Section 2.4.2.

JM-1 is located in the middle portion of the West Jefferson site in the Medical Research and Evaluation Facility (MREF)—a complex consisting of a BSL-3 facility (see Section 2.4.2 for explanation of BSL), a chemical surety materiel research facility, and supporting facilities including barns, equipment/supplies storage, and offices. The JM-1 facility is a 26,185-square foot concrete block, two-story structure, including a 2,620-square foot modular animal holding facility. Originally constructed in 1966-1967, it was renovated and validated for BSL-3 activities between November 1993 and September 1995. The BSL-3 suite in JM-1 is 4,850 square feet. This BSL-3 facility is currently used by 8 Battelle workers on a full-time basis and by 37 Battelle workers on a part-time basis. It is anticipated that the proposed JVAP-sponsored work would require two of the part-time workers to become full time.

JS-1 is a 13,368-square foot structure located in the southern portion of the Battelle West Jefferson site. This facility is a concrete block/metal skin building constructed in 1954-1955 and modified/expanded several times through 1973. The JS-1 building was renovated and validated for BSL-3 activities between August 1993 and January 1994. The BSL-3 suite in JS-1 occupies 750 square feet. Five Battelle workers currently use the JS-1 BSL-3 facilities on a part-time basis. It is anticipated that this usage would increase but still remain part time for the proposed JVAP-sponsored work.

2.3 PROPOSED STUDY ACTIVITIES

The JVAP-sponsored activities proposed at the Battelle West Jefferson site include studies required for advancing biological defense vaccine candidates through the development process. The required activities include both *in vivo* (in living organisms) and *in vitro* (in "glass") laboratory studies to fully characterize a vaccine's chemical composition and purity as well as to determine effective and safe dosages, possible side effects and efficacy. Such studies are used to demonstrate that a vaccine should be safe for use in humans and effective for its intended purpose. Such testing must be conducted in the laboratory and with animal models before a vaccine's first use in clinical testing (with humans). Animal models may include mice, rats, hamsters, guinea pigs, rabbits, nonhuman primates or other appropriate models. As integral components of vaccine development, and required for FDA licensure, these safety and characterization studies must be conducted according to the FDA *Good Laboratory Practice* (GLP) *for Nonclinical Laboratory Studies* which prescribes the required laboratory practices, facilities and equipment, organization and personnel qualifications, experimental protocols and conduct of laboratory studies, and record keeping and reporting (21 CFR Part 58).

The required testing will be conducted using pilot and production lots of candidate vaccines that have been produced elsewhere and transported to the Battelle West Jefferson site. The following is a list of the studies that may be required in testing the vaccine candidates that are under development for medical protection against plague, ricin toxin, botulinum toxins, the encephalitis viruses (Venezuelan, Eastern, and Western equine encephalitis), smallpox virus, tularemia, Q-fever, staphylococcal enterotoxins, and brucellosis:

- Animal testing to determine if vaccine candidates and their constituents are toxic or produce adverse effects (toxicity testing, including reproductive and developmental toxicity; and neurovirulence [i.e., characterize growth in and effect on neural tissue] studies).
- Dose escalation studies to define the optimal dose to evoke a protective response.
- Studies to establish and confirm the LD₅₀ of the etiologic agent in unimmunized animals.
- Develop and use diagnostic methods to determine etiologic agent concentration in test samples.
- Challenge studies in which vaccinated animals are exposed to the etiologic agent by aerosol or parenteral route.
- Immunogenicity testing to determine if the vaccine produces the desired immune response.
- Safety testing and studies of vaccine candidate to determine reactogenicity, pyrogenicity, or other potential side effects.
- Vaccine characterization studies (sterility, identity, purity, and chemical composition).
- Correlating the protective response in animals to the immune response in humans.

2.4 SAFETY POLICIES AND PROCEDURES

The following sections describe the policies and procedures under which the proposed JVAP-sponsored activities must be conducted to ensure valid results, environmental protection, and the health and safety of workers and the public. Incorporation of accepted safety practices and procedures in implementation of the proposed action ensures product safety and effectiveness, environmental integrity, and the health and safety of workers and the public as required by Federal, DoD, DA, state, and local laws, regulations, and policies.

2.4.1 General Safety Requirements

All sites at which JVAP-sponsored activities are conducted (including private laboratories such as Battelle) must adhere to DoD, DA, Federal, state, and local laws and regulations pertaining to the safe use, handling, and disposal of etiologic agents and other potentially hazardous materials such as chemicals. All activities of a hazardous nature performed by either civilian or military personnel at DA work sites (including contractor sites) are governed by *The Army Safety Program* (AR 385-10), which implements by reference all applicable Federal, state, local, DoD, and DA requirements. This comprehensive safety regulation defines safety management and responsibility, personnel training, personal protective equipment and clothing, waste-handling procedures, inspections, spill and emergency procedures, hazard communication, and other elements impacting safety.

Safety review and oversight at Battelle are implemented through a hierarchy of several committees that establish the policies and guidelines for working with hazardous materials. An individual is assigned at JM-1 and at JS-1 who is responsible for implementing environmental, safety, and health activities and for assisting management with safety issues. These environmental, safety, and health

representatives review procedures, conduct hazard analyses and dry runs of procedures, document monthly inspections, and provide daily guidance about safety issues. The environmental, safety, and health representatives have authority to stop activities if unsafe practices are observed.

A written standard operating procedure (SOP) must be available for all recurring activities and must be developed and approved before new work commences. An SOP contains detailed, step-by-step directions for accomplishing a given task in a safe and consistent manner. SOPs for a given activity are prepared prior to the beginning of an operation and must be verified by dry runs (without the actual use of the etiologic agent or hazardous material). SOPs must be reviewed and approved by relevant Battelle safety committees and personnel and the facility manager prior to implementation of the work.

Both JM-1 and JS-1 have established Facility Safety Plans (FSPs) that detail the significant potential hazards associated with their operations as well as the mitigation measures employed to ensure their safe operation. The FSPs for JM-1 and JS-1 contain extensive descriptions of facility attributes such as engineering (e.g., ventilation systems) and work practice controls, emergency preparedness, training, and the other elements essential to safety.

2.4.2 Biological Safety

Guidelines established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) and published in *Guidelines on Biosafety in Microbiological and Biomedical Laboratories* (CDC/NIH, 1993) describe recommended laboratory practices, techniques, facilities, and equipment necessary to contain etiologic agents of varying degrees of pathogenicity and virulence. These measures have been developed to minimize risks to human health and the environment. The DA has established regulations that mandate adherence to these guidelines, thus work funded by the DA and involving etiologic agents used in the JVAP, such as those listed in Section 2.3, must be conducted in accordance with these guidelines and must also meet the safety requirements detailed in 32 CFR Parts 626 (*Biological Defense Safety Program*) and 627 (*Biological Defense Safety Program*, *Technical Safety Requirements*).

The guidelines describe the four BSLs established by the CDC and NIH for conducting laboratory operations with infectious agents and/or their toxins. The guidelines also describe four animal BSLs (ABSLs) for operations involving the use of animals infected with etiologic agents requiring BSLs 1-4 containment. BSL-1 practices, safety equipment, and facilities are appropriate for facilities in which work involves defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. BSL-2 practices, safety equipment, and facilities are appropriate for facilities in which work involves the broad spectrum of indigenous (native) moderate-risk agents present in the community and associated with human disease of varying severity. Work with indigenous or exotic agents that have serious or lethal consequences if inhaled requires BSL-3 containment. BSL-4 practices, safety equipment, and facilities are required for work with dangerous and exotic agents posing a high individual risk of life-threatening disease. ABSLs 1-4 practices, equipment, and facilities also provide increasing levels of containment. The CDC/NIH guidelines include "agent summary statements" that provide information on laboratory hazards associated with specific agents and guidance for selecting appropriate BSLs. Under the CDC/NIH guidelines, the laboratory director is responsible for determining the appropriate BSL based upon "the virulence, pathogenicity, biological stability, route of spread, and communicability

of the agent; the nature or function of the laboratory; the procedures and manipulations involving the agent; the endemicity of the agent; and the availability of effective vaccines or therapeutic measures" (CDC/NIH, 1993). In addition, pre-award surveys and annual inspections will be conducted by safety and occupational health professionals for work requiring BSL-3 and BSL-4 containment and procedures.

The proposed JVAP-sponsored testing and evaluation of vaccine candidates will require the use of BSL-2 and BSL-3 facilities, work practice and engineering controls. BSL-3 "differs from BSL-2 in that (1) more extensive training in handling pathogenic and potentially lethal agents is necessary for laboratory personnel; (2) all procedures involving the manipulation of infectious material are conducted within biological safety cabinets, other physical containment devices, or by personnel wearing appropriate personal protective clothing devices; [and] (3) the laboratory has special engineering and design features, including access zones, sealed penetrations, and directional airflow" (32 CFR 627).

BSL-3 facilities such as those required for the proposed work must have signs posted on entry doors indicating their BSL-3 designation, agent(s) in use within, and individuals to contact in case of an emergency. Measures to limit and control access to BSL-3 laboratories are required and include worker and visitor sign-in and electronic access badges. Access to the BSL-3 laboratories is restricted to personnel directly involved with the work and authorized for entry. Authorization for entry is based on guidelines established by the Battelle Biosafety Committee and enforced by the laboratory manager. The BSL-3 laboratories are locked at all times.

The BSL-3 laboratories operate under negative pressure to the outside, which results in a net flow of air into the facility. In addition, Phoenix valves regulate and monitor negative pressure for each room. Should backup systems fail, a bypass system maintains negative pressure within a specified range. Facility airflow is maintained by magnetic controls that ensure that laboratory doors cannot be opened unless the adjacent outer hallway door is closed. There is backup power for all ventilation/filtration systems required to maintain directional airflow. A digital system constantly monitors airflow, pressure, temperature, and humidity. This information is monitored by a full-time maintenance worker who is a trained heating, ventilation and air-conditioning (HVAC) professional.

All work conducted within the BSL-3 laboratory must be conducted within biological safety cabinets suitable for the given work. Biological safety cabinets (BSCs) provide contained space in which etiologic agents and animals can be safely manipulated. BSCs are certified annually by an outside contractor. Battelle operations and facilities exceed the CDC/NIH requirements for BSL-3 containment in that all air leaving BSL-3 containment passes through two sets of high efficiency particulate air (HEPA) filters before venting to the outside. Each HEPA filter is rated to remove 99.97 percent of particles at a size of 0.3 microns. The first set (a pre-filter and HEPA filter) is located within a BSC, through which all air leaving a BSC passes. A second HEPA filter set is located in the facility maintenance room, a short distance from the laboratories. At the Battelle West Jefferson site, incoming laboratory air is also HEPA-filtered. A contractor tests the HEPA filters (dioctyl phthalate testing) every 2 years.

Potentially contaminated work materials and wastewater are not removed from the BSL-3 facilities until they are rendered inocuous by chemical disinfection or autoclaving. To limit moving

potentially contaminated materials, autoclaves are positioned between rooms or hallway areas enabling items to be sterilized before being passed to outer "clean" areas. The permitted flow of people, equipment, animals, and experimental materials within JM-1 and JS-1 is detailed in FSPs and SOPs. The restrictions on the movement of these entities are designed to protect worker health and safety, prevent cross-contamination in adjacent areas, and prevent the breach of containment.

Wastewater processing at the JM-1 facilities exceeds CDC/NIH guidelines for BSL-3 containment. Liquid wastes are decontaminated prior to leaving BSL/ABSL-3 suites and then flow to a 1,000-gallon holding tank located in the facility maintenance room. When this tank is approximately three-quarters full, its contents are heated to 250°F for 60 minutes as a precaution to inactivate any potential etiologic agent (Stitcher, 1998a). Following this treatment, the wastewater holding tank is discharged to the wastewater treatment facility in the middle area of the complex (see Section 2.6).

Facilities that transfer or receive certain etiologic agents are required to apply for registration with the CDC in accordance with 42 CFR 72.6, *Additional Requirements for Facilities Transferring or Receiving Select Agents*. The Battelle West Jefferson site has met CDC requirements and is registered (Apple, 1997). The transfer of agents to and from Battelle must be documented and reported to the CDC. Within the Battelle West Jefferson site, control and inventory of etiologic agents are conducted according to SOPs established for each facility.

An inspection of the BSL-2 and BSL-3 laboratories in JM-1 and JS-1 was conducted by the U.S. Army Medical Research and Materiel Command (USAMRMC) biosafety officer on April 9, 1997 and March 26, 1998 in accordance with AR 385-69 (32 CFR Parts 626 and 627). The BSL-2 and BSL-3 laboratories, animal facilities, and support facilities were inspected using the Basic Checklist for Biosafety Levels 1, 2, and 3 (DA Pamphlet 385-69, 32 CFR Part 627). The facilities were found to meet or exceed physical standards for BSLs 1, 2, and 3 as described in the CDC/NIH guidelines (CDC/NIH, 1993) and DA Pamphlet 385-69. Operational procedures observed or discussed were also in accordance with applicable regulations. The USAMRMC biosafety officer noted no deficiencies relative to the standards of AR 385-69 (Hawley, 1998). On February 24, 1997, the Madison County Health Department also conducted an inspection of the JM-1 facility and indicated that all aspects of infectious waste handling were in compliance (Powers, 1997).

2.4.3 Chemical Safety

Small quantities (less than 150 pounds per Resource Conservation and Recovery Act (RCRA) standard) of hazardous chemicals will be used in the conduct of the proposed research. The handling and use of hazardous chemicals is regulated by Occupational Safety and Health Administration (OSHA) regulations. The Environmental, Safety and Health Officer (ESHO) has prepared the MREF Chemical Hygiene Plan (CHP) in accordance with OSHA regulations (29 CFR 1910.1450, *Occupational Exposure to Chemicals in Laboratories*) and oversees its implementation. Battelle-wide policies and procedures for the safe handling and use of chemicals are contained in the Battelle CHP as required by OSHA regulations. OSHA regulations require training for all personnel prior to work assignments or new tasks with the potential for exposure to hazardous chemicals. Information and training continue through occasional refresher courses. Training includes instructions for accessing Material Safety Data Sheets (MSDSs). The CHP and laboratory-specific procedures must provide information about handling controlled substances, chemical acquisition, chemical storage, potential health risks, environmental monitoring, personal protective

equipment, use of fume hoods, safety procedures, and inspections and laboratory audits. In accordance with these regulations, Battelle has developed written safety policies and procedures for all laboratory personnel. For information about chemical waste handling and disposal, see Section 2.6.

2.4.4 Radiologic Safety

Although the Battelle West Jefferson site has a valid U.S. Nuclear Regulatory Commission (NRC) license and all associated SOPs, policies, and safety management, it is not anticipated that the use of radioisotopes will be required to conduct the proposed JVAP-sponsored activities.

2.5 SECURITY

The Battelle West Jefferson site is patrolled by armed guards at all times. Bar gates restrict vehicular traffic access onto the facility during off duty hours and video surveillance occurs throughout the site. Access into containment laboratories requires passing through a series of electronic checkpoints and access is restricted to authorized personnel. Visitors to either JM-1 or JS-1 must be escorted and are required to sign in upon entry.

2.6 WASTE STREAM MANAGEMENT

Wastes that will be generated by conduct of the proposed action include general solid waste, animal waste, sharps, liquid infectious waste, hazardous chemical and solid waste, and wastewater. The current volume of these waste types and the projected maximum quantities for the proposed JVAP-sponsored activities are summarized in Table 2-1.

Table 2-1. Annualized Summary of Waste Streams from JM-1 and JS-1

(Battelle, 1998)

Waste Type	Current (Baseline Wastes)	Additional Wastes from Proposed JVAP- Sponsored Activities	Total Projected Waste (Baseline & Proposed)	Disposal Method / Provider
General solid waste (pounds)	30,000	30,000	60,000	Sanitary landfill
Animal wastes (pounds)	182,500	182,500	365,000	Pathological waste incinerator
Sharps (pounds)	300	300	600	Browning Ferris Industries
Liquid infectious waste (gallons)	2	49,988	49,990	Autoclave, sterilization tank, or chemical disinfection
Hazardous chemical waste (pounds)	150	150	300	Hazardous waste contractor
Radiologic waste	0	0	0	N/A
Wastewater (million gallons)	4.38	2.19	6.57	Battelle wastewater treatment plants

Included in these estimated waste quantities are regulated wastes such as sharps (e.g., needles) and potentially contaminated materials, general solid waste, and animal wastes. In accordance with CDC/NIH guidelines (CDC/NIH, 1993), all wastes contaminated or potentially contaminated with infectious material must be rendered noninfectious before disposal. This decontamination is accomplished by a combination of chemical and physical (autoclave) methods. Heat-sensitive chemical strips are included in each autoclave load and test strips containing heat-resistant bacterial spores are included monthly to verify that temperatures capable of inactivating etiologic agent were achieved. The results of these verification procedures are recorded and maintained (Stitcher, 1998a).

The wastewater generated in the JM-1 facility is initially decontaminated and then collected in a 1,000-gallon wastewater holding tank where it undergoes steam treatment prior to discharge to the Battelle West Jefferson site wastewater treatment system. When the tank is about three-quarters full, its contents are heated to 250°F for 60 minutes as a precaution. The temperature and pressure in the tank are measured by instrumentation and recorded and maintained in logbooks. The effectiveness of this wastewater heat treatment is also verified by the use of both chemical and biological testing.

Wastewater exiting the sterilization tank is discharged to the wastewater treatment plant in the middle area through the sanitary sewers. Sanitary wastes from JM-1 are released directly to the wastewater treatment plant. The middle area wastewater treatment plant processes an average of 22,500 gallons per day. A smaller wastewater treatment facility located in the southern area processes wastewater from JS-1. The average flow through this plant is 400 gallons per day. These wastewater treatment facilities provide secondary treatment to wastewater from both laboratories. The Ohio Environmental Protection Agency (OEPA) permits (Permit No. 4IN00004*DD) the plants to operate under the National Pollutant Discharge Elimination System (NPDES) program. The current permit expired May 31, 1996. Battelle submitted a renewal request in November 1995. In August 1997, OEPA issued a draft renewal permit which imposes restrictions related to a new noncontact cooling water system designed to reduce the temperature of the water discharged from the wastewater treatment facilities. Discussions between OEPA and Battelle are currently under way to modify the design of the noncontact cooling water system to ensure that the temperature of the discharge is suitable for Big Darby Creek; with state approval, existing operations continue under the prior permit. Battelle is in compliance with all other limitations of the NPDES permit.

Hazardous waste procedures at the Battelle West Jefferson site implement the OEPA hazardous waste management regulations that have been promulgated under the RCRA. The Battelle hazardous waste identification number is OHT400013892. The quantity of hazardous waste generated from the proposed JVAP-sponsored activities is expected to be approximately 150 pounds.

A Comtro Model A-24 pathological waste incinerator is located adjacent to the JM-1 facility and is rated to burn 200 pounds per hour. The normal operating schedule is 8 hours a day, 5 days a week for 40 weeks a year. The incinerator typically burns paper, cardboard, wood, animal carcasses, and plastic bags and laboratory clothing. The stack height is approximately 34 feet above the ground. Since construction in 1983, the incinerator has been permitted by the OEPA. The latest permit (Application # 0149000077N001) expired September 1, 1997. Battelle submitted a renewal

application for the incinerator prior to the expiration of the current permit; however, OEPA has not acted on this application. In accordance with the Ohio Revised Code (ORC) Section 119.06, the incinerator is permitted to operate under the existing restrictions until OEPA renews the permit. Stack testing of the incinerator emissions by OEPA indicates the incinerator operates within the permit requirements of no more than 20 percent capacity, 0.10 pounds total suspended particulates per 100 pounds charged, and 200 pounds burned per hour.

Battelle has requested that the Infectious and Solid Waste Division of the OEPA amend the current Battelle Infectious Waste Generator's License to include autoclaving as means of treatment for infectious waste. With this change, animal wastes meeting the OEPA definition of infectious wastes can be rendered non-infectious in the BSL-3 autoclaves. The treated, noninfectious wastes, will then be incinerated in the pathological waste incinerator. It is estimated that the ash generated would weigh 3 to 4 percent of the original weight, i.e., a maximum of 7,300 pounds per year (182,500 pounds of animal waste per year x 4 percent = 7,300 pounds of ash per year). The ash would be disposed of in a sanitary landfill (Stitcher, 1998b).

2.7 ANIMAL CARE AND USE

Several regulations and laws require standards for the humane care, handling, treatment, and transportation of research animals. The care and use of laboratory animals must comply with standards specified in AR 70-18, The Use of Animals in DoD and DoD-Sponsored Programs, and the Animal Welfare Act (9 CFR Part 14). Facilities working with etiologic agents in testing biological products must comply with 21 USC 154. The Guide for the Care and Use of Laboratory Animals, Department of Health and Human Services (DHHS) Publication 86-23 (National Research Council, 1996) also sets standards for animal handling practices and the quality of care. The Council on Accreditation of the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC International) evaluates the Battelle West Jefferson site animal facilities and animal care and use programs annually to ensure maintenance of appropriate standards. On July 2, 1998, AAALAC International continued Full Accreditation for Battelle's animal facilities and programs. On July 24, 1998 representatives of USAMRMC also inspected these facilities and programs and noted no deficiencies (Ruble, 1998). Representatives of the USDA have also inspected (May 1998) the animal facilities and noted no deficiencies (Markin, 1998). The Institutional Animal Care and Use Committee (IACUC) oversees all aspects of the animal facilities and program at the Battelle West Jefferson site.

Cage cards identify experimental animals, the treatment they are undergoing, and related biohazards. Animal inventories are required daily, and laboratory animal care logbooks must be maintained. The building in which animals are maintained is kept locked at all times. It is anticipated that the proposed JVAP-sponsored activities may require mice, rats, hamsters, guinea pigs, rabbits, non-human primates or other appropriate models. All studies will be designed to minimize the use of laboratory animals. The actual number of animals required will be based upon the level of JVAP-sponsored activities.

2.8 HUMAN HEALTH AND SAFETY

2.8.1 Occupational Health and Safety

The Battelle Bloodborne Pathogen Exposure Control Plan specifies requirements protective of worker health and safety, including vaccination (immunization) requirements and medical monitoring recommendations in accordance with 29 CFR 1910.1030. Battelle requires all staff with potential for exposure to etiologic agents to participate in the Battelle medical monitoring program. Medical monitoring is a requirement of both the CDC/NIH guidelines and AR 385-69. In accordance with CDC/NIH guidelines and AR 385-69, baseline serum samples (blood samples obtained before working with an etiologic agent) must be obtained from workers. CDC/NIH guidelines also recommend, and AR 385-69 requires, that additional periodic blood studies be conducted for those working with etiologic agents. Baseline serum samples must be frozen and stored for 30 years and medical records maintained for 10 years following employment. Maintenance workers and those who on occasion must enter BSL-3 facilities are protected in the same manner as laboratory workers.

Vaccines, when available, are administered to workers having the potential for exposure to etiologic agents. Whenever possible, vaccines are used that are licensed by the FDA. Some vaccines are under regulatory control of the FDA as Investigational New Drugs (INDs) and must be given after the worker has signed a formal consent form. Prior to vaccination, workers must be informed of the possible adverse reactions to vaccination. Workers unable to undergo vaccination for medical reasons are not permitted to work with etiologic agents or in areas where they may be exposed to etiologic agents.

In the event of potential exposure to an etiologic agent, prompt treatment as medically appropriate (e.g., antibiotic therapy) is initiated under medical supervision provided by Battelle. Treatment may include antibiotics that are known to be effective against the etiologic agent given alone or in combination with other drugs and life support measures.

In addition to information, training, and immunizations, the medical monitoring program for personnel at the JM-1 and JS-1 facilities mandates an annual physical examination including a full spectrum serum chemistry profile and urinalysis, eye examination and tonometry, spirometry, audiogram, electrocardiogram, review of medical history and review of work history.

2.8.2 Public Health and Safety

In accordance with AR 385-69, Battelle coordinates emergency preparedness with local emergency service providers and maintains formalized agreements describing particulars of emergency support. Battelle has formalized coordination with the Jefferson County Fire Department, Prairie Township Fire Department, Madison County Police Department, and the Madison County Health Commissioner. New work is coordinated with these local emergency providers and written agreements with them are reviewed and updated annually.

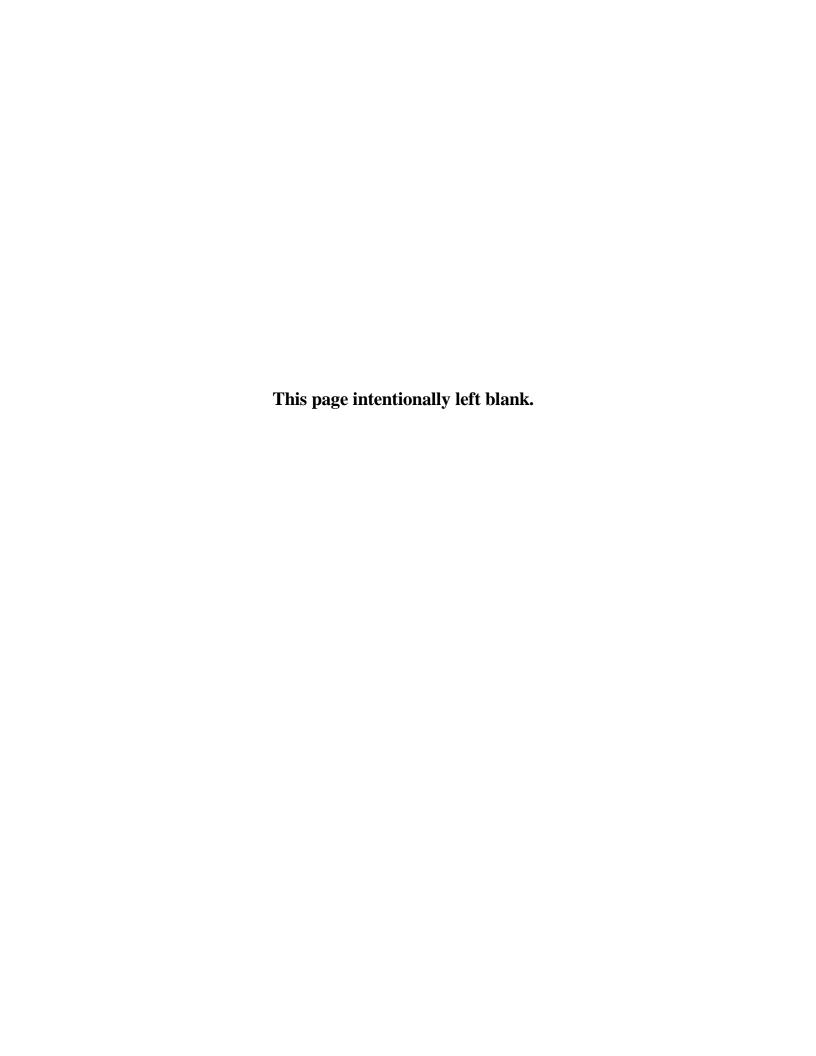
2.8.3 Accidents and Incidents

For the period 1995 to the present, there have been a limited number of incidents recordable on an OSHA 200 log. There were two incidents of workers having reactions to plague vaccine

administered through the Battelle occupational health program. In both of these incidents, the workers responded to rest and treatment with over-the-counter medication (e.g., Tylenol®). Additional incidents were back strain resulting from lifting, a bruised hand from moving furniture, and a small cut to the hand from washing glassware.

2.8.4 Human Research Subject Protection

The proposed JVAP-sponsored activities at the Battelle West Jefferson site will involve the use of human research subjects, but only under the auspices of a special immunization program. Specifically certain employees at the Battelle West Jefferson site will enroll in protocols which meet both FDA requirements for receipt of IND vaccines and CDC/NIH guidelines that workers at risk of exposure to etiologic agents be immunized prior to beginning work when vaccines are available (CDC/NIH, 1993).



3.0 ALTERNATIVES CONSIDERED

3.1 Introduction

The proposed action and subject of this EA is the conduct of JVAP-sponsored activities at the Battelle West Jefferson site, located in West Jefferson, Ohio (Alternative I, the preferred alternative). During the preparation of this EA, two reasonable alternatives to the proposed action were identified. These alternatives were to conduct proposed JVAP-sponsored activities at another location (Alternative II), and not conduct proposed JVAP-sponsored activities (Alternative III, no action).

3.2 ALTERNATIVE I – CONDUCT PROPOSED JVAP-SPONSORED ACTIVITIES AT THE BATTELLE WEST JEFFERSON SITE

Alternative I entails the activities necessary to conduct the currently proposed JVAP-sponsored vaccine development activities at the Battelle West Jefferson site in West Jefferson, Ohio. Battelle will conduct these activities for JVAP through a subcontract to the JVAP PSC, DynPort, LLC. This alternative is preferred because of the suitability of facilities and expertise available at this facility.

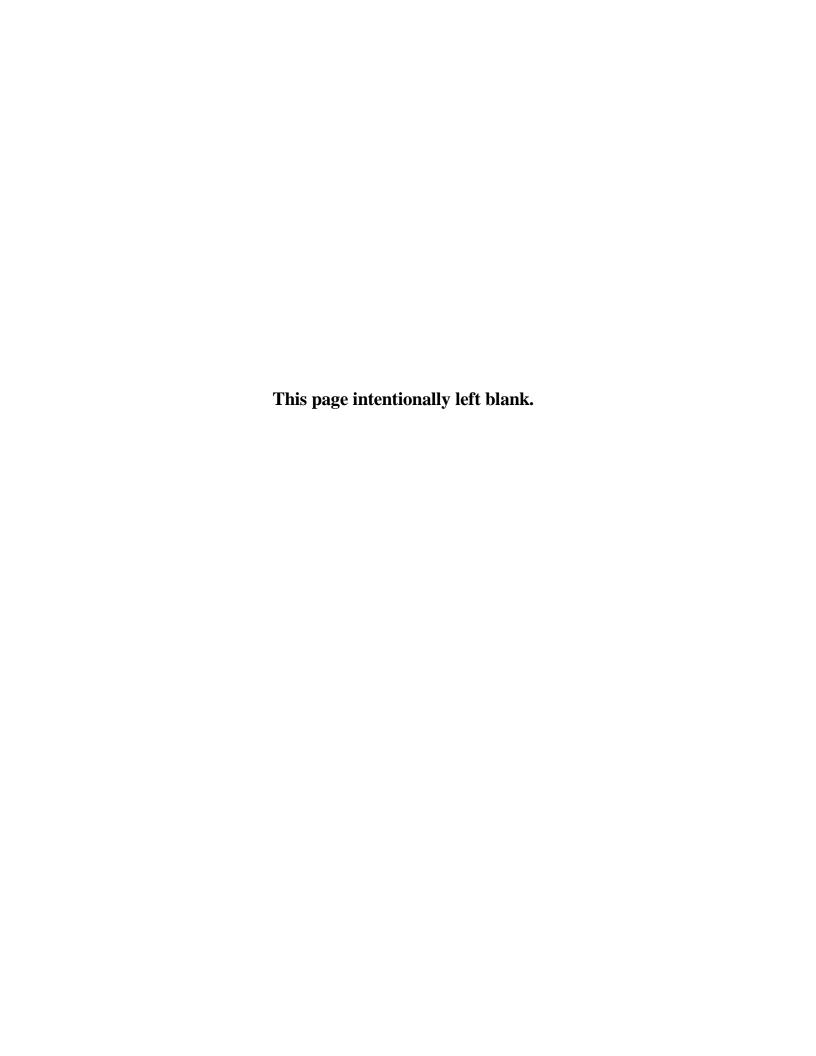
3.3 ALTERNATIVE II – CONDUCT PROPOSED JVAP-SPONSORED ACTIVITIES AT ANOTHER FACILITY

Alternative II entails conducting the proposed JVAP-sponsored activities at another facility. This alternative is not the preferred alternative because it may require the renovation of another facility or the construction of a new facility, activities that will cause some adverse environmental impacts. In the event that renovation or new construction would not be required, the environmental impacts of Alternative II are likely to be similar to Alternative I.

3.4 ALTERNATIVE III – NOT CONDUCT PROPOSED JVAP-SPONSORED ACTIVITIES

Alternative III (no action) entails not conducting the proposed JVAP-sponsored activities. This alternative is not preferred because of the need to maintain continuing efforts toward developing safe and effective vaccines against validated biological warfare threats. In addition, the proposed study activities are required to obtain FDA licensure for the products developed. The JVAP-sponsored activities leading to the development and FDA licensure of biological defense vaccines implement U.S. policy and have been approved by the Joint Chiefs of Staff and funded by the U.S. Congress. Alternative III is not preferred because it would impair national defense by disrupting efforts directed toward protecting U.S. forces from biological warfare threats.

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4.0 AFFECTED ENVIRONMENT

4.1 Introduction

This section of the EA describes aspects of the biophysical and socioeconomic environment (i.e., resource areas) that could potentially be impacted by the proposed action.

4.2 LOCATION AND PHYSICAL DESCRIPTION

Battelle Memorial Institute is located on 1,187 acres known as the Battelle West Jefferson site about 2 miles northeast of West Jefferson, Ohio in eastern Madison County (see Figure 4-1). Madison County covers about 296,320 acres in central Ohio and is located about 17 miles west of Columbus (Soil Conservation Service, 1981).

4.3 LAND USE

In 1997, 268,000 acres of the total 296,320 acreage (90 percent) of Madison County were used for agricultural purposes. There were 680 farms averaging 394 acres (Ohio Agricultural Statistics Service, 1997). Other permitted land uses in this rural area include residential, industrial, restricted industries, commercial, flood plain, suburban residence, central business, highway business, and community shopping center. A residential subdivision is located southwest of the Battelle West Jefferson site. A Girl Scout camp located northeast of the Battelle West Jefferson site across Big Darby Creek is used on weekends and in the summer (Battelle, 1998).

The Battelle West Jefferson site is used for contract research, development, testing and evaluation purposes except for 814 acres leased to farmers, and Battelle Lake which is used for recreation by Battelle employees. There are three research, development, testing and evaluation areas designated as the north, middle, and south areas. The JM-1 facility is located in the middle area and the JS-1 facility is located in the south area. The middle area also has a laboratory facility, animal holding facilities, barns, offices, and storage for equipment and supplies.

4.4 CLIMATE

The climate of the West Jefferson/Columbus area is characterized as humid and temperate with cold winters and hot summers (Soil Conservation Service, 1981). Mean monthly temperatures range from 73.2 degrees Fahrenheit (°F) (summer) to 26.4°F (winter), with the highest temperatures usually occurring in July and the lowest temperatures occurring in January (National Weather Service, 1993). Average high and low temperatures recorded for Columbus over 29 years range from 83.7°F to 18.5°F. Precipitation in the winter frequently consists of snow causing soil moisture to accumulate sufficiently to minimize drought in some soils in the summer (Soil Conservation Service, 1981). The average annual precipitation is about 38.1 inches, with monthly averages ranging from 2 to 4 inches. The average annual snowfall for the Columbus area is approximately 27.6 inches (National Weather Service, 1993). Most of the precipitation, 59 percent of the annual total, falls between March and August. Prevailing winds are from the south-southwest. Summer thunderstorms occur on average about 40 days per year, and severe thunderstorms and tornadoes

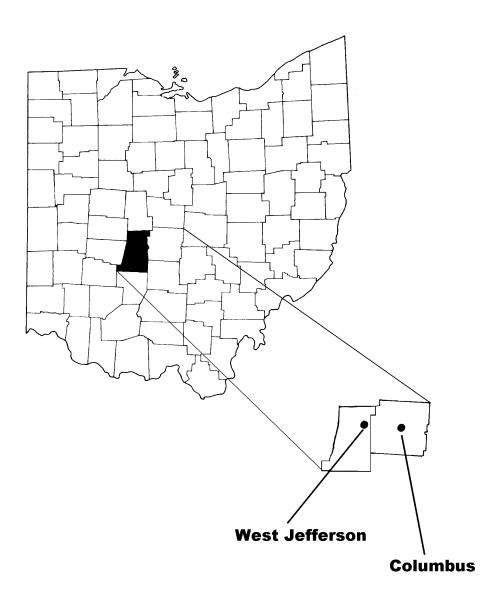


Figure 4-1. Location of West Jefferson, Madison County, Ohio

occur occasionally (Soil Conservation Service, 1981). Between 1950 and 1995 eight tornadoes occurred in Madison County. The most severe was a Force 3 tornado that occurred in 1973 (National Weather Service, 1998).

4.5 GEOLOGY

Formed during the late Precambrian Era about 1 billion years ago, basement or Precambrian rocks lie deep under Ohio. Seas that covered Ohio during the Cambrian Period 500 to 570 million years ago deposited sandy and calcareous sediments on the basement rocks before receding. Seas of the Ordovician Period deposited clayey and limy sediments in western Ohio 435 to 500 million years ago. Various seas covered portions of Ohio during the Silurian and Devonian Periods depositing

carbonate sediments in western Ohio. Later deposits eroded away prior to the Ice Age [Ohio Department of Natural Resources (ODNR), 1998a].

Glaciers from Canada covered western Ohio at least three times in the last 2 million years, most recently the Wisconsin glacier. Two major advances of the Wisconsin glacier covered Madison County. Deposits of glacial till, predominantly loam, remained when the glacier receded from the region. Sand and gravel outwash pockets deposited when the first advance melted was buried under the glacial till left by the second advance. The terrain of Madison County is characterized by almost-level, gently rolling ground moraine and five end moraines that were formed by the retreat and advance of the ice. The dominant geologic feature of the northern portion of Jefferson Township in Madison County is the Darby Plains. This area is level or nearly level. Elevations range from about 1,200 feet above sea level in the west-central part of the county to less than 800 feet above sea level in southeastern portion of the county (Soil Conservation Service, 1981; ODNR, 1998a). The Battelle West Jefferson site lies at about 900 feet above sea level and Battelle Lake lies approximately 888 feet above sea level [U.S. Geological Survey (USGS), 1973; USGS, 1994].

4.6 SOILS

In Madison County, soils derived from the glacial till deposited by the Wisconsin glacier are less than 20,000 years old. The soils of the Darby Plains are generally very poorly drained, productive, and medium to moderately fine textured soils (Soil Conservation Service, 1981).

Soils underlying the middle area of the Battelle West Jefferson site are of the Crosby-Lewisburg silt loams, 0-2 percent slopes. This soil unit is 45 to 65 percent Crosby and 25 to 45 percent Lewisburg soils. The Crosby soils are typically nearly level and somewhat poorly drained. Crosby soil has a surface layer characterized by dark grayish brown, friable silt loam about 10 inches thick. The subsoil is a dark yellowish brown and brown, mottled clay loam approximately 21 inches thick. The substratum extends to about 60 inches and is yellowish brown, mottled, firm clay loam. Carbonates may be found at depths less than 18 inches. Crosby soil is slowly permeable with moderate to high available water capacity and slow runoff. The seasonal high water table is found at depths between 12 and 36 inches. The typical Lewisburg soil has a brown, friable silt loam surface layer approximately 8 inches in depth. The dark yellowish brown and yellowish brown, firm clay loam of the subsoil is about 14 inches thick. The substratum extends to about 60 inches in depth, is more than 22 inches thick in some areas, and is mottled, yellowish brown, firm loam (Soil Conservation Service, 1981).

Underlying the south area are Lewisburg-Celina silt loams, 2-6 percent slopes, which are typically moderately well drained, gently sloping, and found on ground moraines and end moraines. The unit is generally 40-60 percent Lewisburg silt loam and 25-35 percent Celina silt loam. The surface layer of Celina soil is brown, friable silt loam about 9 inches thick. The subsoil is approximately 17 inches thick and is characteristically yellowish brown in the upper layer and mottled in the lower portion. The substratum is brown and yellowish brown, mottled, firm clay loam and loam extending to depths of about 60 inches. South of the middle area and west of the southern area is nearly level Kokomo silty clay loam, 0-2 percent slopes. This soil is typically poorly drained and commonly found along or near small intermittent waterways or between low knolls. The Kokomo soil has a very dark gray, friable silty clay loam surface layer about 10 inches thick. The subsoil is about 22 inches thick and composed of firm, mottled clay loam very dark grayish brown in the

upper layer and dark grayish brown and grayish brown in the lower portion. The substratum extends to about 60 inches and is characterized by gray and grayish brown, calcareous, mottled, firm loam. In better-drained areas, the substratum is a calcareous firm loam found at depths of less than 30 inches. Miamian silt loam, 12-18 percent slopes, is found between Battelle Lake and the middle area and north of the southern area. Miamian silt loam is typically found between gently sloping uplands and stream terraces, and is well drained and moderately steep. South and east of the southern area is Miamian silt loam, 18 to 25 percent slopes, a steep, well drained soil with moderately slow permeability and moderate available water capacity (Soil Conservation Service, 1981).

4.7 WATER RESOURCES

4.7.1 Surface Water

The OEPA uses the U.S. Environmental Protection Agency (USEPA)-designated ecoregions, which are based on land-surface areas with similar land use, potential natural vegetation, land surface form, and soils to characterize surface waters (OEPA, 1996a). Madison County lies in the Eastern Corn Belt Plain, which is characterized by more than 75 percent cropland agriculture, pasture, small or medium urban areas, and small woodlots. There are no heavy industrial centers in the area. The Eastern Corn Belt Plain is a gently rolling glacial till plain with features of end moraines, outwash plains, and kames. Some streams in the region have been channelized to improve field drainage and/or prevent flooding (USEPA, 1988).

Ohio Water Quality Standards [Ohio Administrative Code (OAC) 3745-1] water use categories include aquatic life, public water supply, agricultural water supply, industrial water supply, and recreational. The OEPA uses biological as well as chemical criteria to assess the condition of an ecosystem. Aquatic life use designations are tiered. There are four classes of attainment status for aquatic life use: full attainment of use; full attainment of use but attainment is threatened; partial attainment of use; and non-attainment of use (OEPA, 1996a).

Big Darby Creek flows southward through central Ohio to the Scioto River, dividing Madison County from Franklin County to the east. Because of the diversity of freshwater mussels and fish found in these waters, 82 river miles of Big Darby Creek and its major tributary Little Darby Creek were designated state scenic rivers in 1984, and national scenic rivers in 1994. The Nature Conservancy has designated Big Darby Creek as a "Last Great Place." The OEPA monitored Big Darby Creek between 1979 and 1995. Big Darby Creek was found to have high quality waters with limited nonpoint source impacts in the upper basin. The overall condition of the aquatic community was unchanged between 1979 and 1995. In the Big Darby Creek watershed, 50 to 75 percent of the river is in aquatic life use attainment. Locations on Big Darby Creek have Index of Biotic Integrity and Invertebrate Community Index (i.e., biological community indices) scores in the exceptional range (OEPA, 1996a).

The majority of the county ultimately drains into the Scioto River. The largest drainageway in the county is Deer Creek, which drains areas west and south of the Village of West Jefferson. Little Darby Creek drains the northern portion of Madison County, flows north into Union County, and then flows southeast past West Jefferson into Big Darby Creek in Franklin County. Paint Creek and small tributaries of Big Darby Creek located south of Plain City drain the remaining portions of

Madison County (Soil Conservation Service, 1981). The area north and west of the MREF drains into Battelle Lake while the land south and east drains east into Big Darby Creek. Battelle Lake, an impoundment of Silver Ditch, is a private lake and therefore not monitored by OEPA. Big Darby Creek flows about 500 feet east of the Battelle West Jefferson site. Parts of Madison County, including the Village of West Jefferson and the Battelle West Jefferson site, lie in the Upper Scioto Watershed, the Scioto River basin, and the Ohio River drainage basin. The Darby Creek Watershed drains 556.6 square miles.

In August 1997, the Battelle West Jefferson site received a permit to install a cooling tower for noncontact cooling water for the West Jefferson laboratory (Application No. 01-7117). Battelle Memorial Institute also filed a draft NPDES permit renewal (Permit No. 4IN00004*DD; expiration date May 31, 1996). The receiving waters for this discharge are Big Darby Creek.

4.7.2 Groundwater

Central Ohio lies over aquifers of the Central Lowland Physiographic Province. The consolidated-rock Silurian-Devonian aquifer consists primarily of dolomite and limestone and extends to about 500 feet below the surface. Also known as the carbonate aquifer in Ohio, the aquifer extends from western Illinois to central Ohio. The Silurian carbonate rocks are hydrologically more important than the Devonian rocks. Unconsolidated surficial deposits of Quaternary age overlie the aquifer in many areas. Water of the surficial aquifer system is typically hard, of a calcium magnesium bicarbonate type with iron in high concentrations. The Silurian-Devonian aquifer is recharged from the surficial aquifer system in areas where the water level is higher in the surficial aquifer system than in the Silurian-Devonian aquifer. The freshwater derived from the Silurian-Devonian aquifer can generally be treated and made adequate for most purposes. Calcium, magnesium, bicarbonate, and sulfate are the most common ions found in water samples from western Ohio (USGS, 1995).

The OEPA is responsible for management of groundwater quality in Ohio. The Division of Drinking and Ground Waters is the lead agency that administers the State Coordinating Committee on Ground Water, which consists of Federal, state, and local agencies. These agencies conduct various programs to evaluate, monitor, and protect Ohio groundwater resources. Estimated total groundwater pumpage for all uses is 1 billion gallons per day. In western Ohio, lower Devonian and Silurian limestones and dolomites are 300 to 600 feet in total thickness, and wells may yield 100 to more than 500 gallons per minute. As of 1996, there was one ambient groundwater monitoring site located in a major aquifer setting in Madison County. The major aquifer setting of this site is described as Silurian carbonate bedrock overlain by unconsolidated glacial and alluvial sand and gravel deposits (OEPA, 1996b).

The Battelle West Jefferson site operates and maintains its own water supply. Battelle currently obtains all drinking water from three groundwater wells approximately 100 feet deep at the Battelle West Jefferson site. The total pumpage volume is approximately 35,000 gallons per day. Water in the middle area is treated with softeners prior to use by JM-1. Wastewater from the softeners also goes to the middle area treatment plant. The water supplied to the southern area, and therefore JS-1, is untreated (Caslow, 1998). The water to JM-1 is metered whereas the water to JS-1 is not metered. JM-1 activities use 5,853,474 gallons and JS-1 activities use approximately 785,400 gallons of water annually. In accordance with the Federal Safe Drinking Water Laws and Chapter 6109 of the ORC, the OEPA monitors water quality of public drinking water supplies (OEPA,

1996a). The Battelle West Jefferson site has an OEPA license (No. 98-4930212; expiration 30 January 1999) to operate and maintain a public water system. Monitoring by OEPA indicates that water quality of the well water is consistently within Federal and state standards.

4.8 PLANT AND ANIMAL ECOLOGY

More than 814 acres of the 1,187 acres of the Battelle West Jefferson site is leased for agricultural purposes. The wooded areas, pasture, agricultural lands, wetlands, and streams found on or near the Battelle West Jefferson site provide a diverse habitat for a variety of plant and animal species. Vegetation in the West Jefferson area is typical of the Eastern Corn Belt Plains hardwood forests: American beech, sugar maple, white oak, black oak, northern red oak, yellow poplar, hickory, white ash, and black walnut. Silver maple, cottonwood, pin oak, sycamore, elm, and sweetgum are found near streams and rivers (USEPA, 1988). Oak, hickory, sycamore, maple, basswood, cottonwood, willow, and ash may be found in wooded areas near the Battelle West Jefferson site. The Darby Plains area of Ohio was a tallgrass prairie less than 200 years ago, and some small prairies still exist in Madison County. Some prairie plant species may be found in the area. Other herbaceous plants in the region include grasses and goldenrod.

Common game species in the area include white-tail deer, red and grey foxes, cottontail rabbits, and squirrels. Game birds include quail and some ducks. Birds, such as sparrows, cardinals, hawks, geese, herons, and pheasants, and animals (including raccoons, woodchucks, and chipmunks) and reptiles and amphibians (including frogs, salamanders, and snakes) are assumed to inhabit the area (ODNR, 1998b). Battelle Lake, which also supports recreational activities for Battelle employees such as fishing, has been stocked in the past. Battelle is permitted by OEPA to discharge up to 45,000 gallons per day of noncontact cooling water to Battelle Lake. A robust fishery in the lake includes largemouth bass, channel catfish, bluegill sunfish, yellow perch, and black crappie.

No state-listed rare species of plants or animals or exemplary natural communities are found on the Battelle West Jefferson site. The Division of Natural Areas & Preserves of the ODNR is not aware of any geologic features, breeding or non-breeding animal concentrations, champion trees, state parks, forests or wildlife areas within 1 mile of the Battelle West Jefferson site based on a review of Natural Heritage maps and files (Woischke, 1998). However, the Battelle West Jefferson site and adjacent areas provide potential habitat for a number of special status species. The Indiana bat (*Myotis sodalis*) is considered an endangered species by the Federal government and the state of Ohio. The state of Ohio considers endangered the following five species of birds which may find suitable habitat in the area: the American bittern (*Botaurus lentiginosus*), the loggerhead shrike (*Lanius ludovicianus*), northern harrier (*Circus cyaneus*), magnolia warbler (*Dendroica magnolia*), and the dark-eyed junco (*Junco hyemalis*). There are no records of these special status species at the Battelle West Jefferson site or adjacent areas. Big Darby Creek, which is adjacent to the eastern portion of the Battelle West Jefferson site, is a pristine water body with a diverse aquatic biota including many species of fish and invertebrates. This water body and associated areas provide habitat for 11 special status animal species and 14 special status plants (Table 4-1).

Table 4-1. Special Status Species Inhabiting Big Darby Creek

(Woischke, 1998)

	Federal	State	State
Species	Endangered/	Endangered/	Special
	Threatened	Threatened	Interest
Fish			
Northern brook lamprey (Ichthyomyzon fosser)		X	
Northern madtom (Noturus stigmosus)		X	
River redhorse (Moxostoma carinatum)		X	
Scioto madtom (Noturus trautmani)	X	X	
Spotted darter (Etheostoma maculatum)		X	
Mollusks			
Wavy-rayed lampmussel (Lampsilis fasciola)			X
Clubshell (Pleurobema clava)	X	X	
Northern riffleshell (Epioblasma torulosa rangiana)	X	X	
Rabbitsfoot (Quadrula cylindrica cylindrica)		X	
Round pig-toe (Pleurobema sintoxia)			X
Snuffbox (Epioblasma triquetra)		X	
Plants			
Arbor vitae (Thuja occidentalis)			X
Grape Honeysuckle (Lonicera reticulata)			X
Green milkweed (Asclepias viridiflora)			X
Large yellow lady's-slipper (Cypripedium calceolus var. pubescens)			X
Prairie false indigo (Baptisia lactea)			X
Round-leaved dogwood (Cornus rugosa)			X
Scaly blazing-star (Liatris squarrosa)			X
Showy lady's-slipper (Cypripedium reginae)		X	
Southern hairy rock-cress (Arabis hirsuta var. adpressipilis)			X
Spider milkweed (Asclepias viridis)			X
Spotted coral-root (Corallorhiza maculata)			X
Tall larkspur (Delphinium exaltatum)			X
Two-leaved water-milfoil (Myriophyllum heterophyllum)		X	
Weak spear-grass (Poa languida)			X

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4.9 WETLANDS

Wetlands are defined as land where the water table is at, near, or above the land surface long enough each year to cause formation of characteristically wet soil types and support water-dependent vegetation. Wetlands cover about 1.8 percent of the state of Ohio (USGS, 1995). All wetlands in Ohio are designated as State Resource Waters, and the state protects wetland water quality. Over the past 200 years, more than 98 percent of Ohio wetlands have been lost. Wetlands provide many valuable functions, including critical habitat for many species of wildlife including waterfowl and white-tailed deer.

The three classes of wetlands present in the area are lacustrine, palustrine, and riverine. Battelle Lake, the most prominent wetland in the area, is classified as a lacustrine, limnetic, unconsolidated-bottom, permanently flooded impoundment and is located on Silver Ditch. Several smaller distinct wetlands are also located less than 1 mile from the Battelle West Jefferson site. Two small wetlands, each less than one acre in size, are classified as a palustrine, unconsolidated-bottom, saturated, intermittently exposed, and impounded wetlands. One of these wetlands is associated with Silver Ditch northwest of Battelle Lake and the other wetland is just south of the lake. A third wetland classified as a palustrine, unconsolidated-bottom, saturated, intermittently exposed, and impounded lies less than .5 mile north of Battelle Lake and is larger than one acre. A palustrine, temporarily flooded wetland forested in broad-leaved deciduous trees is located near Big Darby Creek north of Battelle Lake. A second wetland classified as palustrine, forested in broad-leaved deciduous trees, and temporarily flooded is located farther west along Big Darby Creek. Adjacent to these wetlands are wetland areas classified as riverine, lower perennial, unconsolidated-bottom, and permanently flooded [U.S. Fish and Wildlife Service (USFWS), 1995; USFWS, 1993].

4.10 AIR QUALITY

Under the Clean Air Act (CAA), the USEPA promulgated the National Ambient Air Quality Standards (NAAQS) to control the criteria pollutants [i.e., O_3 (ozone), sulphur dioxide (SO₂), carbon monoxide (CO), nitrogen oxides (NO_X), lead (Pb), and particulate matter less than or equal to 10 microns in aerodynamic diameter (PM₁₀)]. The OEPA Air Quality Standards (OAC 3745-21-02) are identical to the NAAQS. The Air Quality and Analysis Unit of the OEPA regulates and oversees monitoring of air quality in Ohio. The OEPA is responsible for maintaining 153 air monitoring sites operated by 10 local air agencies. The stations sample ambient air for the six criteria pollutants. The air quality data obtained from the monitoring stations are used to verify compliance with USEPA standards. Areas not meeting the NAAQS are designated as "non-attainment" areas.

Areas not meeting the NAAQS are designated as "non-attainment" areas. Ground-level ozone is formed when the sun reacts with Volatile Organic Compounds (VOCs), (e.g., vapors from paint and gasoline, exhaust from motor vehicles) and NOx (e.g., exhaust from motor vehicles and smoke stacks). Local weather conditions also influence ozone levels with higher values tending to occur on hot, clear days with a light wind. Ozone is measured hourly from April through October, and currently exceeds USEPA health standards when levels are above 0.12 parts per million (ppm). For a violation of the O₃ standard to occur, there must be an average of more than one exceedance per year over a 3-year period.

Madison County is located in the Columbus Air Quality Control Region, which contained a total of 17 ambient air monitoring sites in 1996. The air quality in Madison County is generally good (Ambrose, 1998). The 1996 Ohio Air Quality Report indicates that Madison County was in attainment for the six criteria pollutants except for O₃ (OEPA, 1996c). At the O₃ monitoring site in Madison County, the 8-hour O₃ concentration equaled or exceeded 0.085 ppm on 15 days in the summer of 1998. The high concentrations of O₃ occurred on bright, sunny days with little or no wind, during the late spring and summer. The values were typical for counties surrounding Columbus. In 1997, the USEPA adopted a more stringent O₃ standard of 0.08 ppm averaged over 8 hours. It is anticipated that with the new USEPA O₃ standard, all counties surrounding Franklin County (Columbus, Ohio), including Madison County to the west, will be in non-attainment for O₃ after 3 years of data are collected (Ambrose, 1998).

4.11 HISTORICAL AND CULTURAL RESOURCES

Historic and cultural resources include historic sites, architecturally important buildings, and unique geological locations. Protection of these resources is mandated by the National Historic Preservation Act of 1966, as amended [Public Law (PL) 89-665], and implemented by the DA through NEPA, AR 200-2, and AR 200-4 (*Cultural Resources Management*). According to the state of Ohio, there are no significant historic or cultural resources within 1 mile of the Battelle West Jefferson site (Epstein, 1998).

4.12 ENERGY RESOURCES

JM-1 and JS-1 activities, respectively, currently use 1,234,145 kWh and 147,000 kWh of electricity annually. In 1997, FSG Energy Services provided 12,833 million cubic feet (mcf) and 1,470 mcf of natural gas, respectively, to the JM-1 and JS-1 facilities. JM-1 activities consume approximately 1,000 gallons of fuel oil annually (see Section 5.2.6).

4.13 SOCIOECONOMIC ENVIRONMENT

In 1992, the population of Madison County was 38,952, an increase of 5,948 from 1980 (County and City Data Book, 1998). The county's population grew to 41,184 by 1996 (Office of Strategic Research, 1997). The 1997 population was estimated at 41,486, an increase of 4,418 from 1990 (Ohio State University Extension, 1998). The population of the village of West Jefferson was 4,505 in 1990 (U.S. Census, 1990). The Office of Strategic Research of the Ohio Department of Development estimated West Jefferson's 1996 population at 4,502 (Ohio State University Extension, 1998). Of persons age 25 years or older, 1,199 were high school graduates and 198 had attained a bachelor's degree or higher. According to 1990 U.S. Census data, the median household income for West Jefferson was \$30,688 in 1989. The per capita income for the same year was \$12,044. There were 1,653 housing units in West Jefferson. In 1990, the median sale price for a home in the West Jefferson area was \$63,200 (U.S. Census, 1990).

In 1996, the Madison County civilian labor force was 20,000, with an average unemployment rate of 3.3 percent (Office of Strategic Research, 1997). In September 1998, the unemployment rate was 2.5 percent (Ohio Bureau of Employment Services, 1998). Battelle currently employs 133 full-time and 9 part-time employees at the Battelle West Jefferson site (Battelle, 1998).

According to the 1990 U.S. Census, the population of Jefferson Township was 6,987 and the population of the Village of West Jefferson was 4,505. The West Jefferson population was 99.8 percent white, <1 percent Asian, and 0 percent black, American Indian, Eskimo, Aleut, or Pacific Islander. In 1990, <1 percent of the population was of Hispanic origin. In 1989, 7 percent of all persons in West Jefferson were living below the poverty level (U.S. Census, 1990). In Madison County, 8.4 percent of persons were living below the poverty level in 1989 and 10.8 percent in 1993 (Office of Strategic Research, 1997). According to Ohio Poverty Indicators, in 1995 10.1 percent of persons in the county lived below the poverty level (Ohio State University Extension, 1998).

Approximately 1,100 people live within a 1-mile radius of the middle area. West Jefferson is located 2 miles southwest of the West Jefferson site; however, the closest subdivision is about 0.5 miles east of the south site. In the summer and on weekends, Camp Ken-Jockety has a population of approximately 100. This Girl Scout camp is located about three-eighths of a mile northeast of the Battelle West Jefferson site across Big Darby Creek (Battelle, 1998).

4.14 Noise

There is one record of a complaint regarding noise originating from the Battelle West Jefferson site in the last 5 years. On October 12, 1995, an accidental explosion of the Gas Research Institute pipeline located at the Pipeline Simulation Facility, a Battelle facility unrelated to JM-1 and JS-1, resulted in loud noise which startled nearby neighbors (Battelle, 1998).

4.15 ODORS

There have been no citizen complaints regarding odors originating from the Battelle West Jefferson site in the last 5 years (Battelle, 1998).

4.16 TRANSPORTATION

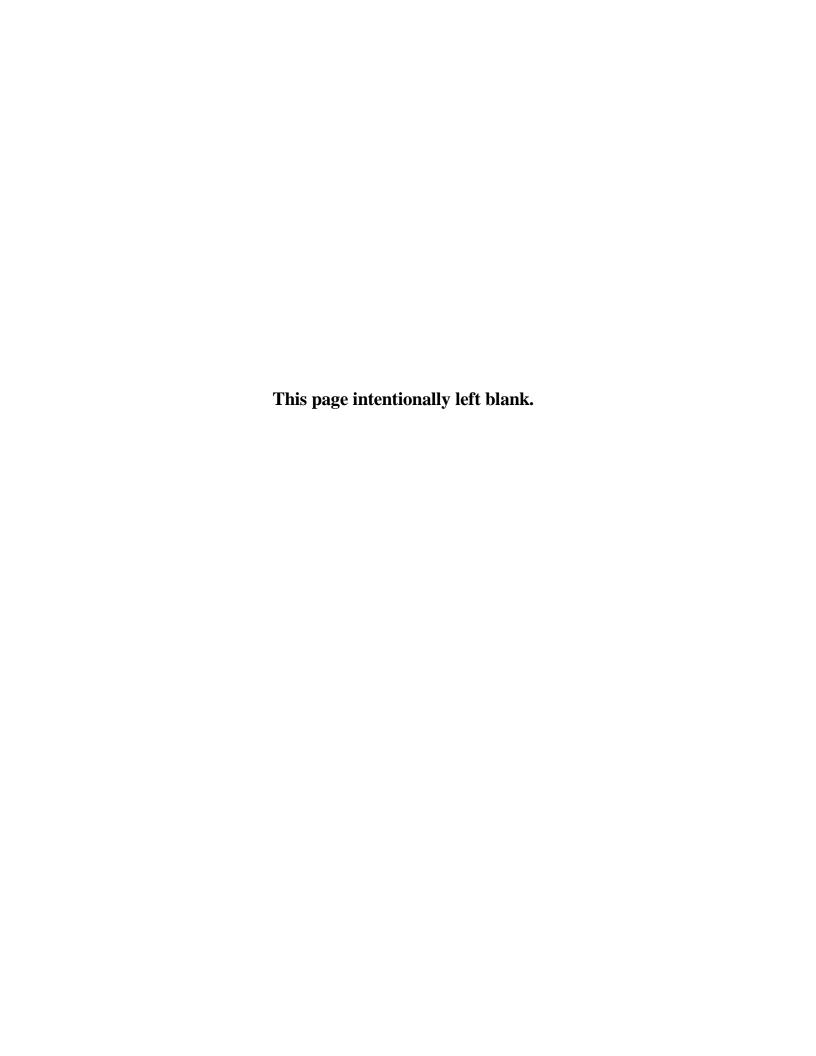
West Jefferson is located about 17 miles west of Columbus, Ohio, which is accessible by highway, air, and rail. Major highways in the West Jefferson area include Interstate Route 70, which runs in an east-west direction north of the Battelle West Jefferson site, and U.S. Highway 40 (National Pike), which runs through West Jefferson south of the site in an east-west direction. State Route 142 (Plain City-Georgesville Road) runs north-southwest of the site. The entrance to the Battelle West Jefferson site is located about 1 mile south of Interstate Route 70 on State Route 142.

From the Battelle West Jefferson site, the Port Columbus International Airport is accessible by automobile via Interstate Route 70 east to Route 71 North to Interstate Route 670 east to airport exit. The airport lies 7 miles northeast of downtown Columbus, 27 miles from West Jefferson, and is served by international and domestic airlines (Columbus Airport Authority, 1997). The Battelle West Jefferson site is located under the flight path for the Port Columbus International Airport.

Amtrak provides a passenger rail line to Columbus. Greyhound Bus Lines also serves bus passengers in the Columbus area.

4.17 Public Opinion

Battelle Memorial Institute is active in local community relations. There are no known adverse public opinion issues.



5.0 ENVIRONMENTAL CONSEQUENCES

5.1 Introduction

In this section, the potential for significant environmental impacts (direct, indirect, and cumulative) likely to result from the proposed JVAP-sponsored activities at the Battelle West Jefferson site will be discussed. This discussion will identify cause and effect relationships between the proposed action and impacts to the environment, including examining impacts that may not necessarily occur but that are reasonably predictable. The term "consequence" refers to the outcome of an event or events without considering probability. Where possible, potential events will be characterized in terms of both their potential consequence and the probability (likeliness) that they will occur.

5.2 Environmental Consequences

5.2.1 Land Use, Geology, and Soils

It is highly unlikely that the proposed activities (Alternative I) would impact land-use patterns, geology, or soils in West Jefferson. All proposed activities will be conducted in existing facilities that have been sited in conformance to local topography and are located within an area that has been used for similar research activities for more than 40 years. The quantity of wastes generated from the proposed activities will be insignificant when compared to the wastes generated by activities within the surrounding region. There are no landfills in Madison County. Solid wastes from the Battelle West Jefferson site will be disposed of in adjacent Franklin County. On average, the Franklin County landfill receives 1,344,000,000 pounds of waste per year, including Battelle's waste. Battelle activities generate 37,300 pounds of waste per year (i.e., 30,000 pounds of general solid waste per year and the expected maximum of 7,300 pounds of incinerator ash per year). This quantity is less than 0.0028 percent of the total waste received annually by the landfill (Dodge, 1998). It is estimated that JVAP-sponsored activities will generate at most an additional 30,000 pounds of solid waste annually. This increase over current levels will bring Battelle's contribution to the Franklin County landfill to 0.005 percent of the total received from all sources. The quantity of wastes disposed of in local landfills will be a negligible component of the total wastes for the surrounding region. Because construction is neither planned nor anticipated, no disruption of landuse patterns or geological resources is likely. Agricultural resources are unlikely to be adversely impacted by the proposed JVAP-sponsored activities at the Battelle West Jefferson site. Similar activities have been conducted at this site without appreciable impacts to the adjacent agricultural resources.

Implementing Alternative II would likely result in negligible impacts similar to those anticipated by Alternative I. Implementing Alternative III (no action) would eliminate any negligible impacts to land-use patterns, geological resources, or soils.

5.2.2 Climate and Air Quality

The proposed JVAP-sponsored activities have the potential to impact air quality through waste contributions to incinerators, energy resource use, personnel and supplier vehicle emissions, and onsite air emissions. It is unlikely that significant negative impacts to air quality would result from the conduct of the proposed activities (Alternative I). The contributions of these impacts to regional air

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quality are likely to be minor in comparison to those of other activities in the area. Current regional air quality is generally good except for O_3 (see Section 4.10). The OEPA Air Quality Standards (OAC 3745-21-02), including provisions applicable to incinerators, are designed to reduce air pollution by considering air quality conditions in each region of the state before determining restrictions for point sources. The incinerator at the Battelle West Jefferson site is in compliance with all relevant standards for this region of Ohio. Continued adherence to CAA provisions related to incinerators will ensure that SO_2 and NOx concentrations will remain below limits determined to aggravate O_3 levels in the Columbus region.

Implementing Alternative II will likely result in comparable minor impacts to air quality at another location. Implementing Alternative III (no action) would eliminate the minor impacts associated with conducting the proposed action.

5.2.3 Water Resources and Wetlands

Implementation of the proposed action (Alternative I, preferred alternative) is unlikely to significantly impact water resources near the Battelle West Jefferson site or in the region. Quantitatively, wastewater contributions expected from proposed activities are likely to increase the discharge to Big Darby Creek by a maximum of 10 percent. This additional discharge is within the volume limitation of the NPDES permit. However, the NPDES permit for the wastewater treatment plant has very stringent restrictions on the discharge to Big Darby Creek, including temperature, because of the highly sensitive nature of this aquatic resource. In accordance with both Federal and state regulations, wastewater generated by the Battelle West Jefferson site activities undergoes treatment at the on-site wastewater treatment plant prior to discharge. The wastewater treatment has been in compliance with all permit restrictions, and Battelle personnel are consulting with the OEPA regarding specifications for the new noncontact cooling tower. Potentially contaminated wastewater generated in the containment laboratories must be rendered noninfectious prior to release outside the containment suite and discharge to the sanitary sewer system. Wastewater generated within JM-1 containment laboratories undergoes additional steam treatment prior to discharge. Equipment and procedures used for decontaminating wastewater undergo certification and verification to ensure their effectiveness (see Section 2.6).

Adherence to Federal and state law and Battelle policy governing wastewater disposal mitigates potential impacts to surface water resources. Potential impacts to Big Darby Creek will be minor to negligible. Groundwater resources are unlikely to be significantly impacted by the proposed action since groundwater usage will only increase negligibly. Adverse impacts to wetlands from implementing the proposed action (Alternative I) are highly unlikely. The proposed action will be conducted in existing facilities and no construction is planned or anticipated; therefore, stormwater runoff patterns will not be altered and there will be no disturbance of existing wetlands. Wastewater will not be discharged to wetlands.

If conducted at facilities with similar controls, implementing Alternative II would likely result in impacts similar to those of the proposed action. Implementing Alternative III (no action) would eliminate the negligible impacts associated with implementing the proposed action.

5.2.4 Plant and Animal Ecology

It is unlikely that adverse impacts to plant or animal ecology will result from the conduct of the proposed activities (Alternative I). No construction or renovation is planned that could impact plant or animal habitat. The etiologic agents that will be used in studies do not cause plant disease. Impacts to animals inhabiting areas near the facilities are highly unlikely because of the design of physical facilities and the containment procedures and practices. The facilities in which experimental animals exposed to etiologic agents will be housed have barriers that reduce the likelihood of animal escape. Among these features are self-closing doors, sealed wall penetrations, no windows, and systems that are species appropriate. In the unlikely event that an animal escaped, it would be unlikely to survive in the natural environment. The Biological Defense Research Program Final Programmatic Environmental Impact Statement (BDRP FPEIS) evaluated this scenario and found that the probability that an animal bred for laboratory research could escape from a BSL-3 facility and survive in the wild was extremely remote (DA, 1989). The BDRP FPEIS further states that no such escapes have been recorded. As discussed in Section 5.2.3, continued adherence to NPDES permit restrictions will protect the sensitive species in Big Darby Creek.

Impacts potentially associated with implementing Alternative II would likely be similar to those of Alternative I. Alternative III (no action) would eliminate any potential adverse impacts to local plant and animal ecology.

5.2.5 Historic and Cultural Resources

Adverse impacts to historic or archaeological resources are unlikely to result from implementation of the proposed alternative. The proposed action will be conducted indoors in existing facilities that have been designed for their intended use. No renovation or new construction is planned that would negatively impact resources. There are no known significant historic or cultural resources within 1 mile of the Battelle West Jefferson site.

Conducting these activities at another location (Alternative II) is also unlikely to significantly impact historic or cultural resources unless renovation or new construction would be required and historic or cultural resources were present at the site. Implementing Alternative III (no action) would eliminate any potential for adverse impacts on historic or archaeological resources.

5.2.6 Energy Resources

Negligible impacts to energy resources are likely to result from implementing the proposed action. The proposed research will be conducted in existing facilities in which similar activities are currently conducted; however, the operation of redundant safety features, specifically the redundant ventilation systems that maintain constant directional airflow require energy resources in excess of those required by non-containment laboratories. Implementing the proposed action will impact existing resource utilization; however, the energy usage will negligibly impact energy resource consumption within the region. FSG Energy Services purchases the natural gas that is supplied to the Battelle West Jefferson site from Columbia Gas of Ohio. Over the past year, Columbia Gas of Ohio provided 1,473,832 mcf of natural gas to its customers in Madison County (Byron, 1998). Battelle facilities used a total of 14,303 mcf annually (12,833 mcf used by JM-1 + 1,470 mcf used by JS-1) (Battelle, 1998). The quantity of natural gas consumed by Battelle activities represents

0.97 percent of the total annual natural gas (14,303 mcf/1,473,832 mcf) used by Columbia Gas customers. In addition, FSG Energy Services is only 1 of 8-10 marketers of natural gas in the area (Bolyard, 1998) so the proportional natural gas consumption by the Battelle West Jefferson site may actually be much lower.

Implementing the proposed action at another facility (Alternative II) would likely result in similar impacts to energy resources. Implementing Alternative III (no action) would eliminate these negligible impacts on energy resources.

Between September and November 1998, the Battelle West Jefferson site used 20.5 percent of the electricity supplied to the incorporated Village of West Jefferson by American Electric Power, Ohio. Assuming that the additional electrical consumption resulting from JVAP-sponsored activities is approximately 20 percent (Stitcher, 1999), the Battelle West Jefferson site will use approximately 23.6 percent of the electricity supplied by American Electric Power. As other companies may supply electricity to unincorporated areas near the Village of West Jefferson, the actual proportional electricity usage by the Battelle West Jefferson site may be less (Hollback, 1998).

5.2.7 Socioeconomic Environment and Aesthetics

Implementation of the proposed action (Alternative I) will likely result in negligible positive impacts on the socioeconomic conditions. JVAP-sponsored activities associated with waste disposal such as incineration and heat treatment of wastes may produce odors [Joint Vaccine Acquisition Program Programmatic Environmental Assessment Joint Program Office for Biological Defense (JVAP PEA JPO BD, 1997)]. These odors, however, are likely to be transitory and rapidly diluted in the atmosphere. Continued adherence to the permit requirements of the incinerator at the Battelle West Jefferson site will mitigate these odors to acceptable levels. The activities associated with implementation of the proposed action do not inherently produce excessive levels of noise. It is unlikely that implementing the proposed action will adversely impact the noise levels of the area. It is unlikely that the proposed action will result in negative socioeconomic or aesthetic impacts.

The negligible socioeconomic and aesthetic impacts associated with conducting JVAP-sponsored activities at another geographic location (Alternative II) would likely be similar to the proposed action. Implementing Alternative III (no action) would eliminate the negligible positive impacts to the local economy and minor aesthetic impacts likely to result from implementing the proposed action.

5.2.8 Transportation

Implementation of the proposed action (Alternative I) will likely have negligible impacts on transportation resources in the region of the Battelle West Jefferson site. There is no construction or renovation planned that would alter existing traffic patterns. The commuting of the workforce involved in implementing the proposed action is unlikely to impact the local or regional traffic patterns or flow. Existing roads and parking facilities within the Battelle West Jefferson site are adequate to accommodate the anticipated level of personnel.

Because of the small number of personnel involved in these JVAP-sponsored activities, implementation of Alternative II would likely result in negligible impacts on transportation at

another geographic location. Implementation of Alternative III (no action) will eliminate any potential for positive or negative impacts to transportation resources associated with the proposed action.

5.2.9 Public Opinion

Public opinion has been an issue in the conduct of biological warfare defense research and development activities and was extensively discussed in the JVAP PEA. There is strong congressional and public support for DoD policy of providing service men and women with the best possible protection against biological warfare agents. Potential criticisms, however, include the perceived potential for components of this work to be used for offensive purposes, the efficacy of biological defense vaccines, distrust of the military, and whether the military should be involved in vaccine development. Some public concerns relate to the existence of biological defense programs *per se*; others, to the intent, need for, and benefits of such programs. Some concerns are specific to the impacts of actions, such as the use of animals in vaccine testing or to the use and handling of recombinant deoxyribonucleic acid (DNA) technology. Concerns such as these are not unique to the proposed JVAP-sponsored work but are associated with vaccine and/or other biomedical research, development and testing activities in general. It should be noted, however, that Battelle has an excellent community relations record.

The government and facilities (e.g., Battelle) supported by the government do not engage in work related to the production or use of offensive biological weapons. Such activities are prohibited by the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction* (the Biological Weapons Convention of 1972) to which the U.S. is a signatory. The prohibitions are enforced by Federal law, which provides criminal penalties for biological weapons activities.

Biomedical research, development, testing, and evaluation (RDT&E) directed toward biological defense and the development of medical countermeasures have been examined within the context of NEPA. The environmental analyses conducted to date have identified no significant adverse environmental impacts associated with such work at the sites examined. Site-specific assessments conducted include the *U.S. Army Medical Research Institute of Chemical Defense Environmental Assessment* (USAMRICD, 1992), *Walter Reed Army Institute of Research Environmental Assessment* (WRAIR, 1993a), and the *Walter Reed Army Institute of Research Leased Facilities Environmental Assessment* (WRAIR, 1993b), *BSL-2 Vaccine Facility at the Walter Reed Army Institute of Research at Forest Glen, Maryland Environmental Assessment* (WRAIR, 1994). An EA was published by the U.S. Army Medical Research and Development Command (USAMRDC) in February 1991 that evaluated RDT&E activities at Battelle's Medical Research and Evaluation Facility involving medical countermeasures against chemical agents (USAMRDC, 1991). This EA resulted in a FNSI.

5.2.10 Human Health and Safety

The proposed action involves laboratory and animal test and evaluation studies, some of which will require the use of etiologic agents capable of causing human disease. These may include plague, ricin toxin, botulinum toxins, the encephalitis viruses (Venezuelan, Eastern, and Western equine encephalitis), vaccinia virus, tularemia, Q-fever, staphylococcal enterotoxins, and brucellosis.

Risks to public health and safety and worker health and safety will be mitigated by carefully considered and applied safety/containment procedures and practices, to include annual inspections by a safety and occupational health professional. Decontamination of all potentially infectious liquid, air, and solid wastes prior to disposal will prevent release of infectious agents to the environment. There have been no instances of infection or disease resulting from the conduct of these types of activities in communities adjacent to facilities such as West Jefferson (JVAP PEA, 1997). A limited number of laboratory acquired infections have been recorded in a broad range of laboratories throughout the U.S. (CDC/NIH, 1993; Sewell, 1995).

5.2.10.1 Public Health and Safety

The risk to public health from the conduct of the proposed JVAP-sponsored activities at the Battelle West Jefferson site is extremely small. Because of the redundant safety features required of BSL-3 operating practices, safety equipment, and special facilities design, it is highly unlikely that the public would be exposed to viable etiologic agents originating from either JM-1 or JS-1. Adherence to Federal and state regulations pertaining to the safe handling and disposal of hazardous chemicals and potentially infectious material further mitigates the likelihood of impact to public health and safety. Similar work has been performed at the Battelle West Jefferson site without any observed impacts to public health.

Conducting JVAP-sponsored activities at another geographical location (Alternative II) would also result in negligible risk to public health and safety. Implementing Alternative III (no action) would eliminate the negligible impact to public health and safety associated with the conduct of the proposed study but would also eliminate the potential for positive impact to public health from developing biological defense vaccines.

5.2.10.2 Occupational Health and Safety

The risk to workers from laboratory-acquired infections from the conduct of the proposed activities (Alternative I) is minimized by implementing the required environmental engineering and work practice controls described in Battelle SOPs and in the CDC/NIH guidelines (CDC/NIH, 1993), AR 385-69, and DA Pamphlet 385-69. These controls prevent etiologic agents from contaminating the laboratory environment. Risk of exposure is mitigated by the use of required laboratory work practices designed to reduce the potential for unintentional aerosol production during routine activities. Work practice controls used to prevent contamination of environments external to the BSL-3 laboratory include disinfecting work surfaces, floors, and drains and segregating and autoclaving waste materials, work clothes, and other material prior to removal from containment facilities. In addition to the use of engineering and work practice controls to reduce the risk of exposure to etiologic agents, regular monitoring of worker health is required. Antibiotic therapy must be administered to workers with possible exposures. Prior to working with etiologic agents, individuals are required to undergo vaccination under a special immunization program (CDC/NIH, 1993) when vaccines are available. The vaccines that workers receive may include licensed vaccines (e.g., anthrax) or those regulated by the FDA as INDs (e.g., tularemia). Significant impacts to worker health resulting from similar work have not been observed at the Battelle West Jefferson site (DA, 1989; JVAP PEA, 1997).

Performing JVAP-sponsored activities at another location (Alternative II) would similarly result in minor to negligible impacts to worker health and safety. Implementing Alternative III (no action) would eliminate the minor impacts to worker health and safety associated with the conduct of the proposed activities.

5.2.10.3 Accidents and Incidents

In accordance with requirements of AR 385-69, a maximum credible event (MCE) analysis has been developed for biological defense research at the Battelle West Jefferson site. An MCE analysis is performed to assess the range of possible consequences that could arise as the result of a mishap. The purpose of performing these analyses is to estimate the effectiveness in existing safeguards. Safeguards include such features as the engineering controls and the attributes of facility design that prevent the release of etiologic agent from the facility. An MCE is a realistic worst-case scenario to which credible information about existing safeguards is applied. In this EA, the MCE analysis is used to examine the probability of adverse impact to human health and the environment from an accident related to JVAP-sponsored work at Battelle West Jefferson site. The probability of such an accident occurring is more remote given the operational and facility safeguards required and to date there have been no such incidents associated with similar activities at the Battelle West Jefferson site using toxins. Although the Battelle West Jefferson site lies on the flight path for Port Columbus International Airport, the BDRP FPEIS concluded that an airplane crash into facilities such as JM-1 or JS-1 was not a realistic credible event. Such an occurrence was determined to be extremely unlikely and so destructive to etiologic agents as to not represent a realistic threat to public health and safety (DA, 1989).

The scenario examined involves spilling a 1 liter (1,000 milliliter (ml)) culture containing 1 billion organisms per ml (1 x 10⁹ organisms/ml) or a total of 1 x 10¹² infectious organisms outside of a BSC in the BSL-3 laboratory. For the purpose of this analysis, an infectious dose of the organism spilled was assumed to be 10 organisms, which would be the most infectious organisms used. The spill therefore represents 1×10^{11} potential infectious doses. Of the liter of culture spilled, approximately 1 percent would become aerosolized $(0.01 \times 10^{11} = 10^9)$ potential infectious doses). It was then assumed that of the 1 percent aerosolized, 90 percent would settle as droplets and 10 percent would remain aerosolized, resulting in 1 x 10^8 potential infectious doses (0.10 x $10^9 = 10^8$ potential infectious doses). It was then assumed that 1×10^6 potential infectious doses (approximately 1 percent) would reach the exhaust after 30 minutes and that 99 percent (9.9 x 10⁵) of this would be trapped by the HEPA filter. Using a simple Gaussian plume dispersion model (a mathematical model that conservatively estimates the likely dispersion of particles released into air) to calculate the spread of the organism once released, it is estimated that organisms in the exhaust would be dissipated to less than 30 infectious doses/liter of air at distances less than 2 meters from the stack, and 3 potential infectious doses per liter at distances 7 meters from the stack. Because laboratory work is normally performed during the day, it is estimated that ultraviolet rays from the sun would destroy or inactivate a large number of the organisms potentially released in this scenario of an MCE analysis. Other meteorological variables such as high wind speed, low humidity, and/or high temperatures would further accelerate biological decay of infectious particles. Laboratory personnel who work with etiologic agents are protected by vaccination when available and would receive immediate appropriate medical care (e.g., antibiotic therapy) in the event of a potential exposure such as the one described here. Because no dwellings are within 500 meters of the stack, it is concluded that this MCE would not pose a significant risk to the community. A similar MCE

for botulinum toxin involves an aerosol exposure. Based on the amount of toxin likely to be aerosolized, the concentration of toxin in the exhaust would be below the threshold for impacting human health. Because the exhaust would immediately be diluted in the atmosphere, the concentration of toxin in the hypothetical accident would decrease to even lower concentrations.

5.2.11 Environmental Justice

Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations, requires Federal agencies to consider whether their projects will result in disproportionate adverse impacts on minority or low-income populations. The U.S. Census defines the poverty level as the income level, based on family size, age of householder, and the number of children under 18 years of age that is considered too low to meet essential living requirements without regard to the local cost of living. The U.S. Census considers a poverty area as an area in which at least 20 percent of the population lives below the poverty level. According to the 1990 census, the area adjacent to the Battelle West Jefferson site would not qualify as a poverty area or minority area. Implementation of the proposed action (Alternative I) is highly unlikely to result in significant adverse impacts to minority or low income populations.

Implementation of Alternative II is also unlikely to impact minority or low income populations because the activities are not expected to cause significant adverse impacts to air quality, noise levels, visual resources, transportation systems, odors, utilities, energy supplies, waste generation, or historic or cultural resources. Implementing Alternative III (no action) would eliminate the potential for adverse impacts.

5.3 CUMULATIVE IMPACTS

The CEQ regulations implementing NEPA define cumulative impacts to the environment as those effects resulting from the impact of the proposed action when combined with past, present, and future actions (40 CFR 1508.7). Thus, cumulative impacts are the sum of all direct and indirect impacts, both adverse and positive, that result from the incremental impacts of the action when added to other past, present, and predictable future actions regardless of source. Cumulative impacts may be accrued over time and/or in conjunction with other pre-existing effects from other activities in the area (40 CFR 1508.25).

No negative cumulative environmental impacts have been observed from the conduct of activities similar to the proposed action at the Battelle West Jefferson site. It is highly unlikely that cumulative adverse environmental impacts will result from implementing the proposed action (Alternative I) because the contributions of the proposed activities to local or regional waste streams or resource utilization are negligible. The proposed research activities will be conducted in existing facilities and no construction or renovation is planned.

Implementing JVAP-sponsored activities at another location (Alternative II) is also unlikely to produce significant cumulative impacts because the amounts of wastes and resource utilization would be small. Implementing Alternative III (no action) will eliminate the negligible to minor adverse cumulative impacts associated with implementing the proposed action.

5.4 COMPARISON OF THE PROPOSED ACTION WITH THE ALTERNATIVES

5.4.1 Alternative I – Conduct Proposed JVAP-Sponsored Activities at the Battelle West Jefferson Site

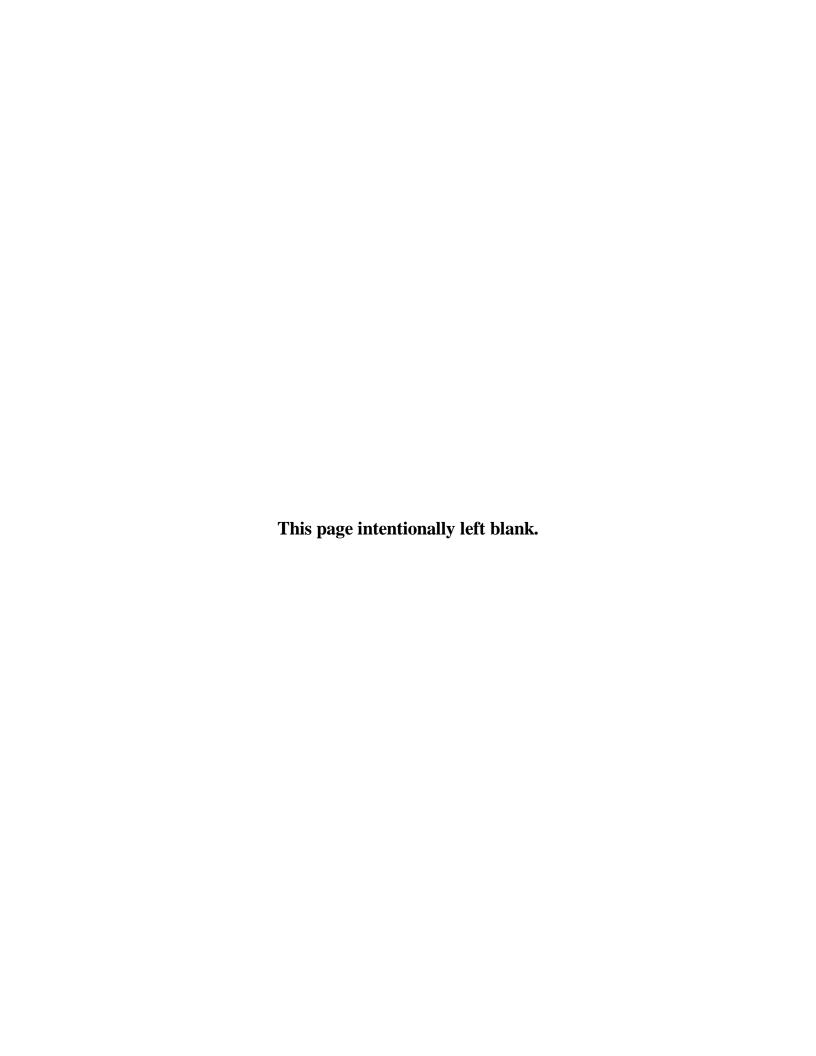
The laboratory methods, hazardous materials, safety, and containment practices employed in the conduct of the biological defense test and evaluation activities for JVAP at the Battelle West Jefferson site are consistent with those required and employed at other biomedical institutions performing similar work (DA, 1989; CDC/NIH, 1993). The potential for adverse impacts to the human environment resulting from the conduct of the proposed activities is extremely small. Positive impacts to U.S. civilian populations and the military are likely.

5.4.2 Alternative II – Conduct Proposed JVAP-Sponsored Activities at Another Facility

Similar to Alternative I, conducting JVAP-sponsored activities at another facility (Alternative II) is likely to result in minor or negligible impacts to the environment unless renovation or new construction is required at the site.

5.4.3 Alternative III – Not Conduct Proposed JVAP-Sponsored Activities

Alternative III, no action, involves not conducting the proposed JVAP-sponsored activities. Implementing this alternative would eliminate the potential negligible adverse impacts associated with the proposed action. This is not preferred, however, because it would also eliminate the potential positive impacts associated with progress toward developing safe and effective vaccines against biological warfare agents.

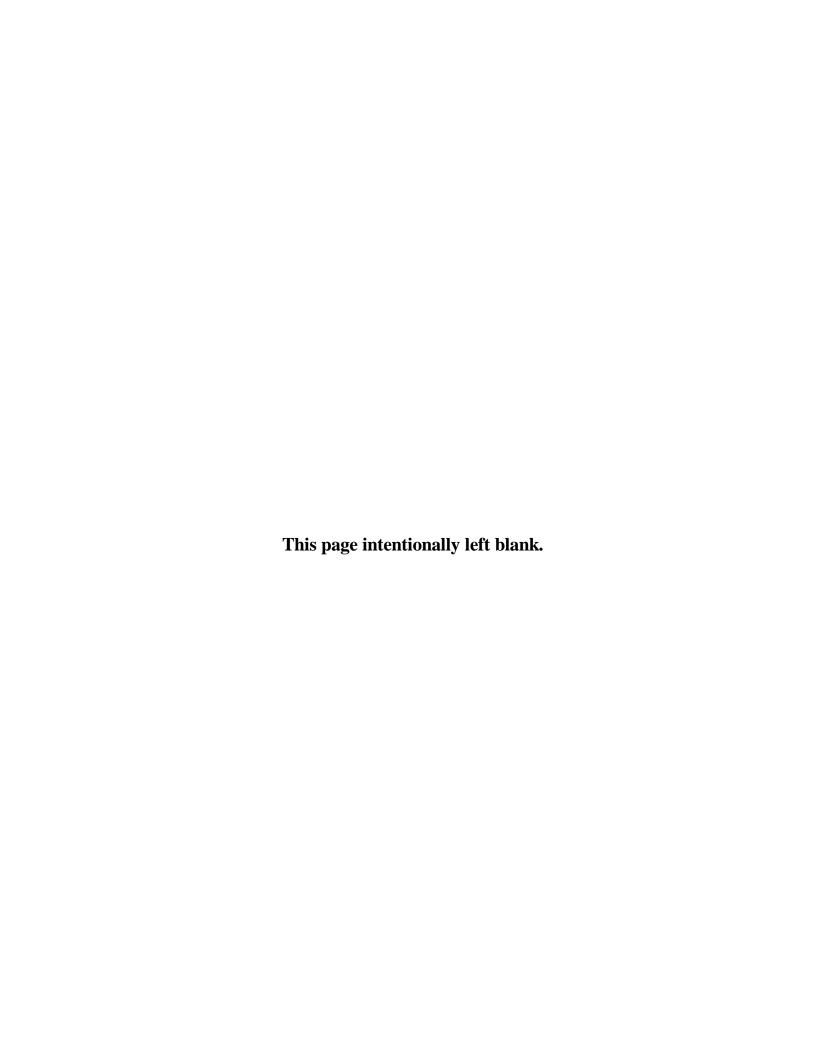


6.0 CONCLUSIONS

The principal conclusions of this EA are: (1) the conduct of the proposed JVAP-sponsored activities (Alternative I, the preferred alternative) is not expected to result in significant adverse environmental impacts; (2) implementing the preferred alternative will likely result in important benefits to the U.S. by enhancing progress toward developing acceptable vaccines against validated biological warfare threats; (3) conducting the proposed activities at another facility (Alternative II) will not likely alter the potential for environmental impact and is unlikely to offer significant advantage over the preferred alternative; and (4) not conducting the proposed JVAP-sponsored activities (Alternative III, no action) will eliminate the negligible environmental impacts associated with conducting development, testing, and evaluation activities but will also impede the development and licensure of biological defense products effective against biological warfare agents.

Laboratory work similar to those required for the proposed JVAP-sponsored work has been conducted at the Battelle West Jefferson site since 1995 without significant environmental impact. The etiologic agents used have been toxins. The potential adverse effects associated with the proposed action are predicted to be negligible, and to date, observed effects associated with similar activities at this site and other comparable sites have been insignificant. Potential risks to human health and the environment will continue to be mitigated by applying required standards, practices, and controls pertaining to the safe use and disposal of hazardous biological and chemical materials, the protection and conservation of natural resources, and the safe and ethical conduct of studies requiring animal subjects.

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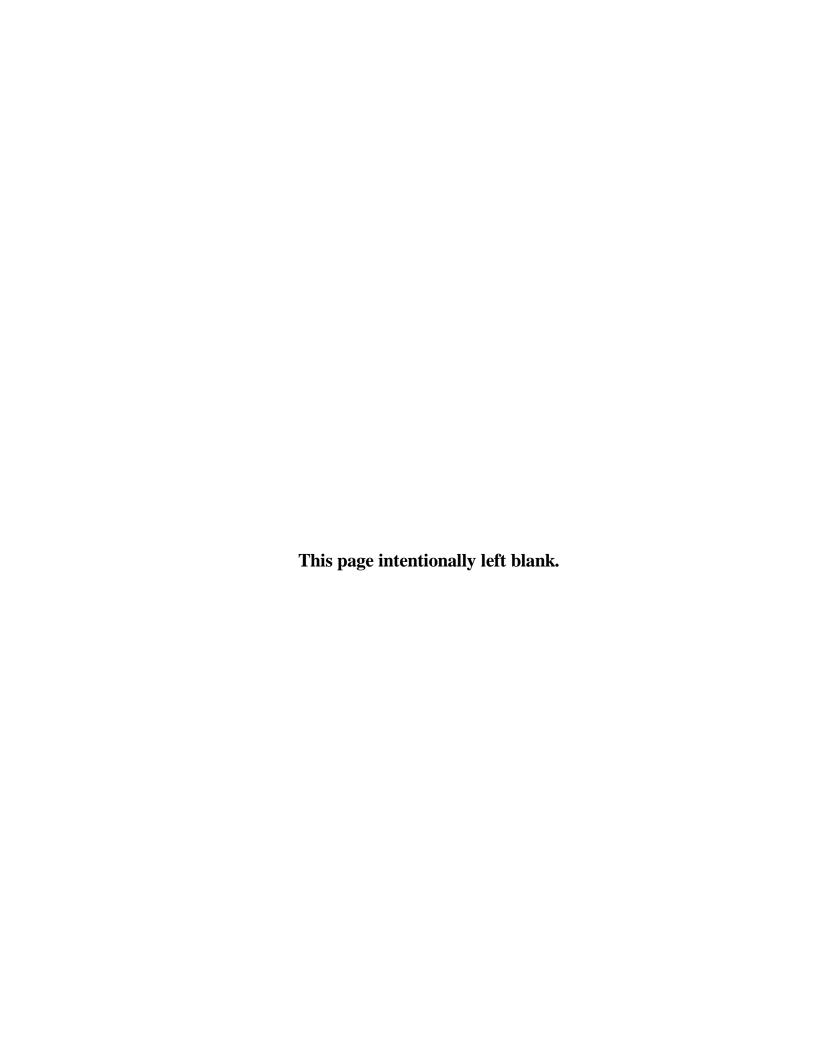
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10.0 ACRONYMS AND ABBREVIATIONS

°F degrees Fahrenheit

AAALAC Association for Assessment and Accreditation of Laboratory Animal Care

AR Army Regulation

BDRP FPEIS Biological Defense Research Program Final Programmatic Environmental

Impact Statement

BSC biosafety cabinet

BSL biosafety level

CAA Clean Air Act

CDC Centers for Disease Control and Prevention

CEQ Council on Environmental Quality

CFR Code of Federal Regulations

CHP Chemical Hygiene Plan

CO carbon monoxide

DA Department of the Army

DHHS Department of Health and Human Services

DNA deoxyribonucleic acid

DoD Department of Defense

EA Environmental Assessment

ESHO Environmental, Safety and Health Officer

FDA U.S. Food and Drug Administration

FSP Facility Safety Plan

GLP good laboratory practices

HEPA high-efficiency particulate air

HVAC Heating, Ventilation and Air Conditioning

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IACUC Institutional Animal Care and Use Committee

JPM-BD Joint Program Manager for Biological Defense

JPO BD Joint Program Office for Biological Defense

JVAP Joint Vaccine Acquisition Program

kWh kilowatt hour

LD₅₀ lethal dose

LLC Limited Liability Corporation

MCE maximum credible event

mcf million cubic feet

ml milliliter

MREF Medical Research and Evaluation Facility

MSDS Material Safety Data Sheet

NAAQS National Ambient Air Quality Standards

NEPA National Environmental Policy Act

NIH National Institutes of Health

NO₂ nitrogen dioxide

NOx nitrogen oxides

NPDES National Pollutant Discharge Elimination System

NRC U.S. Nuclear Regulatory Commission

 O_3 ozone

OAC Ohio Administrative Code

ODNR Ohio Department of Natural Resources

OEPA Ohio Environmental Protection Agency

ORC Ohio Revised Code

OSHA Occupational Safety and Health Administration

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Pb lead

PEA Programmatic Environmental Assessment

PL Public Law

PM Project Manager

PM₁₀ particulate matter less than or equal to 10 microns in aerodynamic diameter

PMO Project Management Office

ppm parts per million

PSC prime systems contract

RCRA Resource Conservation and Recovery Act

RDT&E research, development, test, and evaluation

SAIC Science Applications International Corporation

SO₂ sulfur dioxide

SOP standard operating procedure

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USAMRICD U.S. Army Medical Research Institute of Chemical Defense

USAMRMC U.S. Army Medical Research and Materiel Command

USC U.S. Code

USDA U.S. Department of Agriculture

USEPA U.S. Environmental Protection Agency

USFWS U.S. Fish and Wildlife Service

USGS U.S. Geological Survey

VOC volatile organic compound

WRAIR Walter Reed Army Institute of Research

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